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Original Article

Artificial Intelligence in Drug Delivery Systems: Revolutionizing Pharmaceutical Formulation, Optimization, and Personalized Therapeutics

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ABSTRACT

The rapid evolution of Artificial Intelligence (AI) has redefined the landscape of pharmaceutical sciences, particularly in the area of drug delivery systems. The integration of AI technologies, including machine learning, deep learning, and data-driven modeling, has created new opportunities for designing, optimizing, and personalizing drug formulations with unprecedented precision. Conventional drug delivery approaches often face limitations related to variable pharmacokinetics, inefficient targeting, and unpredictable release mechanisms. AI addresses these challenges by providing predictive insights, optimizing formulation parameters, and enabling adaptive control over therapeutic delivery. This review comprehensively explores the intersection between AI and drug delivery systems, emphasizing how computational algorithms assist in decision-making throughout formulation development, nanoparticle engineering, and smart device-based drug administration. The study highlights the diverse applications of AI across oral, parenteral, transdermal, and implantable delivery systems. The role of AI in predicting drug–excipient compatibility, improving bioavailability, controlling release kinetics, and achieving targeted delivery is critically analyzed. In addition, the application of AI in emerging technologies such as 3D-printed dosage forms, nanocarrier design, and Internet of Medical Things (IoMT) integrated smart delivery devices is elaborated. A special focus is placed on the transformation of data into actionable knowledge through supervised and unsupervised learning models, which enhance the accuracy of pharmacokinetic and pharmacodynamic predictions. Furthermore, the review discusses ethical, regulatory, and implementation challenges that must be addressed to ensure safe and reliable translation of AI-based systems into clinical settings. The paper concludes that AI represents not just a technological advancement but a paradigm shift towards intelligent, patient-centered, and data-driven drug delivery models capable of improving therapeutic outcomes and reducing healthcare costs.

Keywords: Artificial Intelligence; Machine Learning; Drug Delivery Systems; Nanotechnology; Smart Drug Delivery; Personalized Medicine; Deep Learning; Pharmaceutical Formulation; Predictive Modeling; Controlled Release

INTRODUCTION

Drug delivery systems form the foundation of modern pharmaceutical therapy, as they determine how effectively a drug reaches its target site within the body. The primary goal of any delivery system is to ensure that the active pharmaceutical ingredient reaches the intended site of action at the right concentration and duration while minimizing systemic side effects [1]. Over the years, drug delivery technology has evolved from conventional systems such as tablets, capsules, and injections to more advanced approaches including liposomes, nanoparticles, microspheres, and implantable devices [2]. Despite significant progress, challenges such as poor solubility, rapid metabolism, variable absorption, and limited bioavailability continue to limit therapeutic efficiency [3]. Artificial Intelligence (AI) has recently emerged as a powerful tool capable of transforming pharmaceutical sciences, including the field of drug delivery. AI refers to computational systems that mimic human cognitive functions such as learning, reasoning, and decision-making [4]. When applied to drug delivery, AI facilitates the design, analysis, and optimization of complex formulations and delivery mechanisms. It allows researchers to manage large datasets, identify hidden relationships, and predict performance outcomes that

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are difficult to derive through conventional statistical or experimental methods [5]. The integration of AI into drug delivery research has been made possible by the rapid growth of experimental and clinical data. Advanced analytical technologies, high-throughput screening methods, and digital data storage platforms produce massive datasets that can be analyzed using AI algorithms [6]. Machine learning and deep learning models can interpret these datasets to uncover nonlinear relationships between formulation parameters, process variables, and therapeutic outcomes [7]. This capability enables scientists to optimize drug formulations, predict in vivo performance, and accelerate product development while reducing time and cost [8]. In formulation design, AI is now used to predict critical quality attributes such as particle size, dissolution rate, stability, and encapsulation efficiency [9]. Algorithms like artificial neural networks, support vector machines, and random forest models can be trained on experimental data to identify the best combination of excipients and manufacturing conditions [10]. This data-driven approach enhances accuracy, reproducibility, and efficiency in pharmaceutical research, reducing reliance on trial-and-error experimentation [11]. AI also plays a transformative role in personalized medicine. By analyzing individual patient data such as genomic profiles, metabolic rates, and disease progression, AI systems can tailor drug delivery strategies to meet specific therapeutic needs [12]. This individualized approach maximizes efficacy, reduces adverse effects, and improves overall patient outcomes. The integration of AI with biosensors, wearable devices, and mobile health applications has led to the emergence of smart drug delivery systems capable of real-time monitoring and automatic dose adjustment [13]. Moreover, AI contributes to pharmaceutical manufacturing through automation, process optimization, and quality control. Combined with robotics and continuous monitoring, AI enhances production efficiency and ensures product consistency within regulatory standards [14]. These AI-based systems support the Quality by Design (QbD) paradigm, helping industries predict process variations and maintain control over product quality [15]. Despite its advantages, the adoption of AI in drug delivery systems faces multiple challenges. Data quality, algorithm interpretability, and model validation remain key barriers to widespread implementation [16]. The reliability of AI predictions depends heavily on the size and quality of available datasets [17]. Ethical considerations such as patient data privacy, security, and potential algorithmic bias must also be addressed to ensure responsible and transparent AI applications in healthcare [18]. Furthermore, the absence of clear regulatory frameworks for AI-based pharmaceutical systems continues to hinder clinical translation [19]. Nonetheless, the potential of AI to revolutionize drug delivery is undeniable. As the pharmaceutical field becomes more digital and data-driven, AI is expected to play an increasingly central role in enhancing therapeutic precision and patient adherence [20]. When combined with emerging technologies such as nanotechnology, 3D printing, and the Internet of Medical Things (IoMT), AI can create adaptive, intelligent, and responsive drug delivery platforms capable of dynamically adjusting to patient needs [21]. The objective of this review is to explore the role of Artificial Intelligence in the development, design, and optimization of drug delivery systems. It aims to provide a comprehensive overview of fundamental concepts, key applications, technological advancements, challenges, and future perspectives [22]. Through this review, it becomes evident that AI is not merely a computational tool but a transformative force that is redefining the future of pharmaceutical formulation and personalized therapeutics [23].

Image no:2

3: Historical Perspective of Drug Delivery and Artificial Intelligence

The evolution of drug delivery systems represents one of the most significant achievements in pharmaceutical sciences. The concept of controlled and targeted drug administration has developed progressively over the past century, evolving from simple dosage forms to highly engineered systems that combine material science, biology, and advanced technology [24]. In the early stages of pharmaceutical development, most dosage forms were designed solely to deliver active ingredients without considering pharmacokinetic or pharmacodynamic variability [25]. However, as understanding of physiology, biochemistry, and disease mechanisms deepened, the need for more precise and efficient delivery methods became evident.

Evolution of Drug Delivery Systems

The 1950s and 1960s marked the beginning of modern drug delivery, with the introduction of sustained and controlled-release formulations [26]. These systems aimed to maintain constant plasma concentrations of drugs over extended periods, minimizing fluctuations in therapeutic levels. During the 1970s, the focus expanded toward targeted delivery—systems capable of directing therapeutic agents to specific tissues or cells, thereby enhancing efficacy and reducing toxicity [27]. Liposomes, polymeric carriers, and microspheres became popular as early nanocarrier systems designed to improve bioavailability and control release profiles [28]. The late 20th century witnessed rapid advances in polymer science, nanotechnology, and biotechnology, leading to the creation of sophisticated delivery systems such as nanoparticles, dendrimers, and solid lipid nanoparticles [29]. These nanostructured carriers enabled site-specific delivery of drugs and improved penetration through biological barriers. The 1990s and early 2000s brought the rise of smart delivery systems, including pH-sensitive, temperature-sensitive, and stimuli-responsive carriers designed to release drugs under specific physiological conditions [30]. As technology advanced, the concept of “intelligent” or “self-regulated” drug delivery began to emerge, laying the foundation for the integration of Artificial Intelligence in the pharmaceutical field [31].

Emergence of Artificial Intelligence in Science and Technology

The origins of Artificial Intelligence date back to the 1950s, when computer scientists first began exploring the possibility of creating machines capable of simulating human intelligence [32]. Early AI research focused on symbolic reasoning and problem-solving algorithms, but computational limitations restricted practical applications. By the 1980s and 1990s, the development of machine learning and neural networks allowed computers to analyze and learn from data, marking a significant shift from rule-based programming to data-driven modeling [33]. The rapid expansion of computational power, coupled with the availability of large datasets, propelled AI into new domains, including healthcare, biology, and pharmaceutical sciences [34]. In drug research, AI initially found use in computer-aided drug design, molecular docking, and virtual screening [35]. However, as algorithms improved, the scope of AI expanded beyond drug discovery into pharmacokinetics, pharmacodynamics, and formulation design [36]. This evolution created the foundation for its application in modern drug delivery systems.

Transition from Traditional to AI-Driven Drug Delivery

Historically, drug delivery optimization relied heavily on experimental trial-and-error approaches. Researchers would adjust formulation components and process variables through repeated experimentation to achieve desired outcomes [37]. This approach, although effective in some cases, was time-consuming, resource-intensive, and often lacked predictive accuracy. With the rise of computational tools, mathematical modeling and simulation techniques began to replace purely experimental methods [38]. These models provided insights into drug diffusion, degradation, and release mechanisms, but they still depended on simplified assumptions that could not fully capture biological complexity [39]. AI introduced a new dimension by enabling systems to learn directly from empirical data without requiring predefined equations or assumptions. Machine learning algorithms can process thousands of variables simultaneously, identifying patterns and correlations that were previously impossible to discern using conventional models [40]. This capability allows researchers to predict formulation outcomes, optimize compositions, and design delivery systems more efficiently [41]. Deep learning and reinforcement learning further enhance these abilities, supporting adaptive decision-making and continuous improvement in model performance [42]. The application of AI in drug delivery began modestly, focusing on predicting dissolution profiles, optimizing nanoparticle size, and simulating drug absorption [43]. Over time, AI has been employed to design intelligent carriers capable of adjusting release rates in response to physiological feedback. For example, AI-guided insulin pumps and glucose-responsive delivery systems illustrate how data-driven algorithms can maintain homeostasis in real time [44]. Similarly, AI-based models now assist in designing nanocarriers for targeted cancer therapy, optimizing ligand selection, and predicting biodistribution patterns [45].

Integration of AI with Modern Pharmaceutical Technologies

The convergence of AI with other advanced technologies has further accelerated the evolution of drug delivery. The combination of AI with nanotechnology enables automated design of nanoparticles with specific physicochemical characteristics [46]. Integration with 3D printing allows for personalized dosage forms that meet individual patient requirements [47]. The Internet of Medical Things (IoMT) and biosensors provide real-time physiological data that can be analyzed by AI to adjust dosing dynamically [48]. These developments mark the transition from static to adaptive drug delivery systems capable of learning and responding to patient conditions in real time [49]. The historical progression from simple dosage forms to AI-enabled delivery platforms reflects the continuous pursuit of precision, safety, and efficacy in therapeutics. As AI continues to evolve, it promises to transform drug delivery into a predictive, personalized, and adaptive discipline that bridges computational intelligence with biological systems [50]. Understanding this historical context is essential to appreciate the depth of innovation and the transformative potential that AI holds for the future of pharmaceutical sciences.

4: Fundamentals of Artificial Intelligence

Artificial Intelligence (AI) is a multidisciplinary domain that integrates principles from computer science, mathematics, cognitive science, and engineering to simulate human intelligence processes. It involves the development of algorithms that enable machines to perform tasks such as learning, reasoning, perception, and decision-making [51]. AI has evolved into a fundamental technology across multiple sectors, with healthcare and pharmaceuticals emerging as two of its most promising fields. To understand its relevance in drug delivery, it is essential to explore the core concepts, methodologies, and learning paradigms that constitute modern AI systems.

4.1 Core Concepts of Artificial Intelligence

AI encompasses a variety of computational methods and models designed to mimic human cognitive processes. The key functional components of AI include data acquisition, knowledge representation, learning, inference, and adaptation [52]. Data acquisition involves collecting structured or unstructured information from various sources, while knowledge representation organizes this information into logical or statistical models. Learning refers to the algorithm's ability to improve its performance based on experience or data exposure [53].

Modern AI systems rely heavily on large datasets to identify complex relationships among variables. The learning process can be categorized into supervised, unsupervised, and reinforcement learning, each suited to different problem types. Supervised learning models are trained on labeled data, where input-output pairs guide prediction accuracy, while unsupervised learning explores hidden patterns in unlabeled datasets. Reinforcement learning, on the other hand, uses a system of rewards and penalties to optimize decision-making processes [54].

4.2 Machine Learning and Its Role in AI

Machine Learning (ML) represents the foundation of modern AI applications. It is a subset of AI focused on developing algorithms capable of learning from data without explicit programming. ML models use statistical and mathematical techniques to recognize trends, predict outcomes, and automate complex decision-making processes [55]. In the pharmaceutical field, ML is applied to predict drug solubility, optimize formulations, and identify the most effective drug-carrier combinations. For instance, regression-based models can forecast dissolution profiles, while classification models distinguish between effective and ineffective formulations based on physicochemical properties [56]. Clustering algorithms such as k-means and hierarchical clustering are used to group compounds with similar characteristics, aiding in targeted drug development and formulation optimization [57].

Common ML algorithms include:

- Linear and Logistic Regression – for quantitative prediction and classification tasks.
- Decision Trees and Random Forests – for variable selection and interpretability in formulation data.
- Support Vector Machines (SVM) – for pattern recognition in high-dimensional datasets.
- K-Nearest Neighbors (KNN) – for classification based on similarity metrics.
- Gradient Boosting and Ensemble Learning – for improving predictive accuracy across diverse data [58].

These algorithms can be trained using pharmaceutical databases containing physicochemical, pharmacokinetic, or biological data to optimize drug delivery systems at multiple stages of development [59].

4.3 Deep Learning and Neural Networks

Deep Learning (DL) is an advanced subset of machine learning that utilizes multi-layered artificial neural networks (ANNs) to process data hierarchically [60]. Inspired by the human brain's structure, ANNs consist of interconnected nodes or neurons that process and transmit information. Each neuron performs weighted summations of input signals, applies an activation function, and transmits outputs to subsequent layers [61]. This hierarchical feature extraction allows DL models to automatically identify relevant features from raw data without manual preprocessing. Deep learning architectures such as Convolutional Neural Networks (CNNs), Recurrent Neural Networks (RNNs), and Autoencoders have demonstrated exceptional capabilities in image recognition, time-series analysis, and dimensionality reduction [62]. In drug delivery, CNNs are employed to analyze microscopic images of nanoparticles, RNNs to model drug release kinetics, and Autoencoders for data compression in pharmacokinetic modeling [63]. A key advantage of deep learning models is their scalability — they can handle massive datasets with minimal human intervention, providing robust predictive capabilities for formulation design, patient-specific dosing, and therapeutic response prediction [64].

4.4 Reinforcement Learning and Decision-Making Systems

Reinforcement Learning (RL) represents another crucial branch of AI that focuses on optimizing sequential decision-making [65]. Unlike supervised or unsupervised learning, RL agents learn through trial and error by interacting with their environment and receiving feedback in the form of rewards or penalties. This continuous feedback loop allows RL models to improve performance autonomously. In the context of drug delivery, reinforcement learning is applied to develop adaptive systems capable of adjusting dosage or release rates based on physiological signals. For example, RL algorithms have been utilized to optimize insulin dosing in glucose-responsive systems, where the model dynamically modifies the release of insulin in response to real-time glucose levels [66]. Similar approaches are being explored for personalized cancer therapies, where AI-driven decision systems modify treatment regimens based on patient-specific biomarker feedback [67].

4.5 Data Processing and Feature Engineering

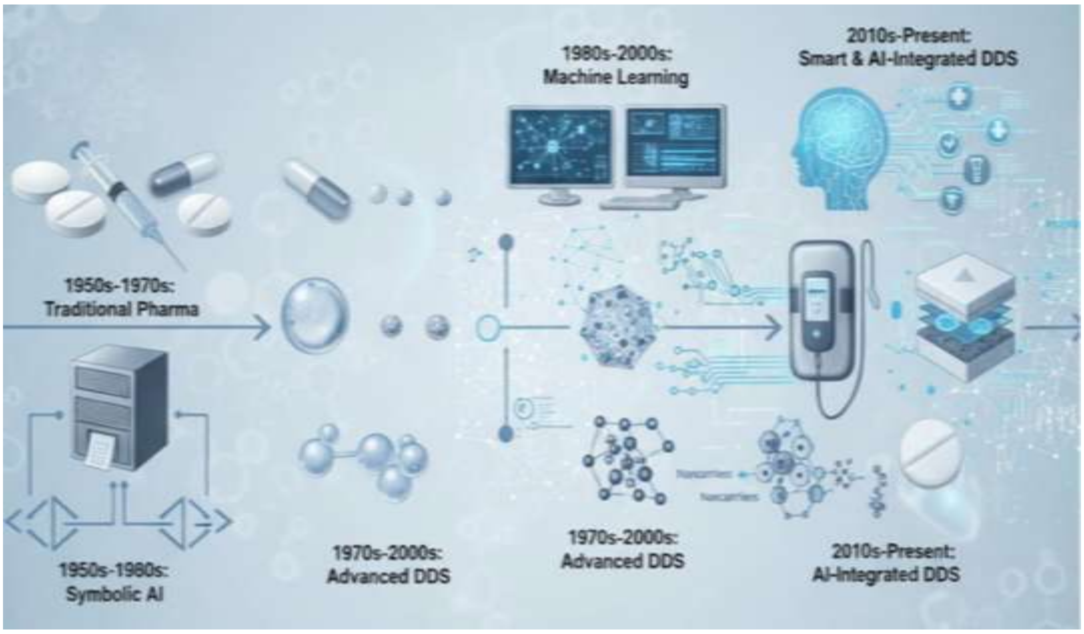
Data is the cornerstone of all AI applications. The quality, quantity, and diversity of data directly influence the performance of AI models. In pharmaceutical sciences, data originates from multiple sources, including preclinical studies, clinical trials, molecular simulations, and sensor-based measurements [68]. To ensure meaningful predictions, data must undergo preprocessing steps such as normalization, noise reduction, missing value imputation, and dimensionality reduction [69]. Feature engineering plays a pivotal role in enhancing model accuracy. It involves selecting, transforming, or creating variables (features) that best represent the underlying problem. In drug delivery, features may include molecular descriptors, particle size, zeta potential, release rate constants, and pharmacokinetic parameters [70]. Proper feature selection helps reduce computational complexity and prevents model overfitting, thereby improving generalizability across different datasets [71].

4.6 Explainable Artificial Intelligence (XAI)

One of the major limitations of deep learning models is their "black-box" nature, which makes it difficult to interpret the decision-making process. Explainable Artificial Intelligence (XAI) seeks to overcome this limitation by providing transparent, interpretable, and human-understandable explanations for AI predictions [72]. In drug delivery, XAI tools are crucial for regulatory approval and scientific validation. Techniques such as SHAP (Shapley Additive Explanations) and LIME (Local Interpretable Model-agnostic Explanations) help identify which features most influence model predictions [73]. This interpretability enhances confidence in AI-assisted formulation development and ensures compliance with ethical and safety standards [74].

4.7 Integration of AI with Data Science and Big Data Analytics

AI and Big Data Analytics work synergistically to revolutionize pharmaceutical research. As high-throughput experiments, omics technologies, and real-time biosensors generate massive data volumes, AI tools analyze and extract valuable patterns [75]. Data science techniques such as statistical modeling, predictive analytics, and visualization complement AI by improving data management and interpretation [76]. This integration enables comprehensive understanding of drug–disease–patient interactions, ultimately leading to more personalized and efficient therapeutic interventions [77]. Artificial Intelligence, encompassing machine learning, deep learning, and reinforcement learning, provides the computational backbone for modern drug delivery innovations. By understanding its fundamental components, researchers can effectively apply these tools to optimize formulation processes, improve patient outcomes, and develop next-generation intelligent drug delivery platforms [78]. The next section explores how these AI fundamentals are applied specifically in the design, development, and optimization of drug delivery systems.



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5: Applications of Artificial Intelligence in Drug Delivery Systems

The integration of Artificial Intelligence (AI) in drug delivery systems represents one of the most transformative advancements in pharmaceutical technology. AI-driven tools and algorithms enable the prediction, design, and control of complex delivery mechanisms with a level of precision previously unattainable through traditional methods [79]. By analyzing vast datasets encompassing molecular, pharmacokinetic, and clinical parameters, AI facilitates efficient formulation optimization, real-time monitoring, and adaptive dosing strategies. This section explores the major applications of AI in drug delivery, including nanoparticle design, targeted drug delivery, controlled release systems, and personalized therapeutics.

5.1 AI in Nanoparticle Design and Optimization

Nanoparticle-based drug delivery systems have gained immense attention due to their potential for targeted and controlled drug transport. However, optimizing nanoparticle characteristics such as particle size, surface charge, drug loading efficiency, and release kinetics remains challenging due to complex interdependencies among formulation variables [80]. AI and machine learning models address this challenge by correlating formulation parameters with performance outcomes, reducing the need for extensive experimental trials. Machine learning algorithms such as Support Vector Machines (SVM), Random Forests, and Artificial Neural Networks (ANN) have been successfully employed to predict nanoparticle size and drug encapsulation efficiency based on formulation inputs [81]. For instance, SVM models can identify optimal polymer-to-drug ratios for polymeric nanoparticles, while ANN models simulate the effects of surfactant concentration and solvent ratios on particle morphology [82]. In addition, deep learning approaches are increasingly used for real-time image analysis of nanoparticles during synthesis. These systems monitor morphology, aggregation, and stability parameters using microscopy and spectroscopic data [83]. Such models allow the development of highly reproducible and scalable nanoparticle formulations, enhancing overall drug delivery efficiency.

5.2 AI in Targeted Drug Delivery Systems

Targeted drug delivery aims to deliver therapeutic agents specifically to diseased tissues while minimizing systemic side effects. This requires precise control over drug distribution, which depends on molecular recognition, ligand-receptor binding, and physiological parameters [84]. AI assists in identifying optimal targeting ligands and predicting biodistribution profiles based on biological and physicochemical data. Machine learning models analyze ligand-receptor affinity, cellular uptake efficiency, and tissue permeability to design delivery systems with high specificity [85]. For example, algorithms can predict the most effective peptide or antibody ligands for tumor-targeted nanoparticles based on binding affinity data. Moreover, reinforcement learning models have been applied to optimize multi-step targeting processes, such as receptor-mediated endocytosis and intracellular trafficking [86]. AI also contributes to multi-scale pharmacokinetic modeling, where computational models simulate how drugs distribute across tissues and cells. These predictive frameworks assist researchers in determining optimal delivery routes (e.g., intravenous, intranasal, transdermal) and dosage regimens for improved therapeutic efficacy [87].

5.3 AI in Controlled and Sustained Release Systems

Controlled release formulations are designed to deliver drugs at a predetermined rate, ensuring consistent therapeutic levels over extended periods. Developing such systems requires balancing multiple factors, including polymer degradation, drug diffusion, and environmental conditions. AI facilitates this optimization by modeling complex release kinetics and predicting how variations in formulation components affect overall release profiles [88]. Neural network-based models have been used to forecast drug release from polymer matrices, microspheres, and hydrogels by analyzing time-dependent dissolution data [89]. Similarly, genetic algorithms and Bayesian optimization methods help identify the ideal combination of excipients and processing parameters to achieve sustained drug delivery [90]. These computational methods can simulate months of release experiments within minutes, accelerating formulation development timelines. Additionally, AI-driven predictive modeling supports the design of stimuli-responsive systems—delivery platforms that release drugs in response to pH, temperature, or enzyme activity [91]. Machine learning frameworks can predict the trigger thresholds of such systems and optimize polymer crosslinking densities for controlled activation, improving site-specific therapeutic action [92].

5.4 AI in Personalized and Adaptive Drug Delivery

Personalized medicine represents the next frontier of pharmaceutical science, and AI is its driving force. Traditional dosing strategies often rely on population-based averages, leading to variable therapeutic outcomes. AI enables the design of individualized drug delivery systems by analyzing patient-specific genetic, metabolic, and physiological data [93]. For example, AI-based pharmacokinetic models can predict individual drug absorption, distribution, metabolism, and excretion (ADME) profiles, allowing for customized dosing regimens [94]. These models integrate data from wearable biosensors, clinical imaging, and electronic health records to continuously adjust drug release rates and dosing schedules [95]. AI-powered feedback systems, such as closed-loop insulin pumps, exemplify adaptive drug delivery. These systems automatically regulate insulin infusion based on continuous glucose monitoring data analyzed by AI algorithms [96]. The same principle is being extended to pain management, oncology, and cardiovascular therapies, where drug release is modulated according to real-time biomarker fluctuations [97]. By merging predictive analytics with responsive delivery mechanisms, AI enables self-regulated therapeutic systems that enhance safety, efficacy, and patient adherence [98].

5.5 AI in Formulation and Process Optimization

AI plays an essential role in pharmaceutical formulation development by streamlining experimental design and manufacturing processes. Conventional formulation relies on trial-and-error approaches and statistical design of experiments (DoE), which are time-consuming and costly. AI tools such as genetic algorithms, fuzzy logic systems, and Bayesian networks automate the search for optimal formulation conditions [99]. For instance, AI models can predict the impact of formulation parameters (e.g., excipient concentration, pH, mixing speed) on product attributes such as viscosity, dissolution rate, and stability [100]. These predictions reduce the number of physical experiments required and improve the reproducibility of results. Furthermore, AI-integrated process analytical technology (PAT) systems monitor manufacturing parameters in real time to ensure consistent product quality [101]. This approach aligns with the Quality by Design (QbD) framework, where AI assists in identifying critical quality attributes (CQAs) and critical process parameters (CPPs), leading to more robust and compliant formulations [102].

5.6 AI in Smart and Responsive Drug Delivery Systems

AI has enabled the emergence of smart drug delivery systems (SDDS)—platforms that can sense, analyze, and respond to physiological changes. These systems incorporate biosensors and AI algorithms to detect biomarkers or environmental cues that signal disease progression or therapeutic need [103]. Examples include AI-assisted glucose-responsive hydrogels, which release insulin when glucose levels rise, and neural network-guided microchips that regulate drug release based on pH or temperature changes [104]. Reinforcement learning algorithms can continuously adjust system behavior to maintain optimal therapeutic levels without external intervention [105]. In oncology, AI-based systems are being developed for tumor microenvironment-responsive delivery, where nanoparticles release drugs upon detecting acidic pH, elevated enzymes, or specific cancer markers [106]. These innovations bring drug delivery closer to true precision medicine by ensuring that treatment occurs only where and when it is needed.

5.7 AI in Predictive Toxicology and Safety Assessment

Safety evaluation is an integral part of drug delivery design. AI models assist in predictive toxicology, enabling early detection of potential toxicity before clinical testing. By analyzing molecular structure data and in vitro results, machine learning algorithms can predict cytotoxicity, immunogenicity, and genotoxicity of delivery materials [107]. For example, AI models trained on nanoparticle toxicity datasets can identify patterns linking particle size, surface charge, and composition to cellular responses [108]. This reduces animal testing and accelerates the safe translation of novel carriers to clinical use. Integrating AI-based toxicological predictions into early development stages enhances the reliability and safety of innovative drug delivery platforms [109]. Artificial Intelligence has thus revolutionized every aspect of drug delivery—from nanoparticle design to smart, adaptive therapeutic systems. Through predictive modeling, data-driven optimization, and real-time feedback mechanisms, AI is paving the way for personalized and intelligent healthcare solutions.

6: AI in Novel Drug Delivery Platforms and Emerging Technologies

Artificial Intelligence (AI) has evolved from a computational tool to a core enabler of next-generation pharmaceutical systems. Beyond traditional dosage forms, AI now powers advanced technologies such as nanorobotics, microchip-based systems, implantable devices, and 3D-printed personalized medicines. These innovations integrate AI algorithms with sensor networks, enabling precise, real-time, and automated control of drug administration [110]. The emergence of such hybrid systems signifies a paradigm shift toward intelligent, adaptive, and patient-specific therapy.

6.1 AI-Driven Nanorobotics in Drug Delivery

Nanorobotics represents one of the most futuristic areas in biomedical engineering, involving nanoscale machines capable of performing specific therapeutic tasks within the body. AI enhances the functionality of nanorobots by providing autonomous navigation, decision-making, and environmental sensing capabilities [111]. Through reinforcement learning algorithms, nanorobots can interpret biological cues such as pH gradients, enzyme activity, or temperature variations, allowing them to deliver drugs precisely to target tissues [112]. For instance, AI-guided magnetic nanorobots have been developed to deliver anticancer drugs directly into tumor microenvironments by navigating through vascular networks with high precision [113]. Machine learning algorithms assist in trajectory optimization, ensuring minimal interaction with healthy tissues. Moreover, AI models can predict nanorobot–cell interactions, optimizing surface chemistry for biocompatibility and efficient cellular uptake [114]. The integration of AI-controlled swarm robotics—where multiple nanorobots operate collectively—enables coordinated therapeutic actions, such as targeted release or localized hyperthermia. This multi-agent coordination is guided by neural network algorithms that analyze local biological signals and synchronize nanorobot movement [115].

6.2 AI-Assisted Microchip-Based Drug Delivery Systems

Microchip-based drug delivery systems offer controlled, programmable release of therapeutics using micro-reservoir arrays and micro-electromechanical systems (MEMS). Incorporating AI into these devices enables real-time monitoring and adaptive drug release based on physiological feedback [116]. AI algorithms analyze continuous data from embedded sensors measuring biomarkers such as glucose, lactate, or hormone levels. Based on this data, the microchip adjusts dosing frequency and intensity autonomously, ensuring precise therapeutic control [117]. Deep learning models are used to predict the pharmacokinetic behavior of the released drug, optimizing future release cycles to match patient-specific needs [118]. Recent advances have demonstrated AI-integrated implantable microchips for chronic disease management. For example, in diabetes therapy, microchips release insulin dynamically in response to fluctuations in blood glucose, guided by machine learning models trained on patient data [119]. These systems eliminate the need for manual dosing, improve patient adherence, and minimize risks associated with over- or under-dosing [120].

6.3 AI in Transdermal and Topical Drug Delivery

Transdermal and topical drug delivery systems are increasingly benefiting from AI-driven optimization. Predicting skin permeability, drug diffusion rates, and absorption profiles across different skin types has traditionally required extensive experimental work. AI models simplify this process by learning from physicochemical, biological, and formulation data to predict transdermal flux and enhance drug penetration efficiency [121]. Machine learning techniques have been applied to identify optimal combinations of penetration enhancers, polymers, and solvents for maximizing drug absorption [122]. Neural network-based predictive tools also simulate the effect of temperature, hydration, and formulation viscosity on skin absorption, thereby streamlining formulation development [123]. Furthermore, AI-enabled wearable transdermal patches are emerging as intelligent platforms capable of monitoring biomarkers through integrated sensors and adjusting drug delivery accordingly. These systems can continuously track physiological changes, such as sweat glucose or electrolyte levels, and modify release kinetics in real time [124]. Such closed-loop feedback systems are transforming chronic therapy by ensuring consistent, responsive, and minimally invasive treatment administration [125].

6.4 AI in Inhalable Drug Delivery Systems

Inhalable drug delivery offers a direct route to the respiratory tract, making it a preferred approach for pulmonary diseases and systemic delivery. AI contributes to this field by optimizing aerosol particle design, deposition patterns, and dose uniformity [126]. Computational fluid dynamics (CFD) combined with AI algorithms predicts airflow dynamics within the respiratory tract, allowing for personalized inhaler design and efficient lung deposition [127]. Machine learning models can analyze patient-specific inhalation patterns to tailor aerosol release timing and particle characteristics [128]. In addition, reinforcement learning is used to optimize dose distribution across lung regions, minimizing drug wastage and improving bioavailability [129]. AI-powered smart inhalers equipped with sensors and Bluetooth connectivity provide feedback on patient adherence, inhalation force, and technique accuracy [130]. Data collected from these devices are analyzed using predictive models to adjust dosing strategies and support clinical decision-making, significantly improving treatment outcomes in conditions like asthma, COPD, and pulmonary fibrosis [131].

6.5 AI and 3D Printing in Drug Delivery

Three-dimensional (3D) printing has revolutionized pharmaceutical manufacturing by enabling the fabrication of complex, customized dosage forms. AI plays a critical role in optimizing design parameters, printing conditions, and drug release profiles [132]. Machine learning models predict how variations in layer thickness, infill density, and excipient composition affect drug dissolution and mechanical stability [133]. AI algorithms can also simulate the entire 3D printing process, minimizing material waste and ensuring consistency across batches [134]. The combination of AI and 3D printing supports personalized medicine, where each dosage form is tailored to a patient’s age, metabolism, and disease state [135]. For example, AI can design tablets with multi-compartment structures, enabling multi-drug release at different time intervals within the same dosage form [136]. Furthermore, AI-integrated 3D printing is being applied in oncology, where printed implants deliver chemotherapeutics directly into tumor sites for sustained local release [137]. This synergy between AI and additive manufacturing is expected to transform pharmaceutical production by enabling flexible, on-demand, and patient-centered formulation strategies [138].

6.6 AI in Implantable and Bioelectronic Delivery Devices

Implantable drug delivery devices are designed to provide long-term, localized, and programmable release of therapeutics. AI enhances these systems by facilitating real-time control, predictive maintenance, and adaptive dosing [139]. Machine learning algorithms can forecast when a device may require refilling or replacement and predict patient responses based on sensor feedback [140]. Bioelectronic devices, combining electrical stimulation with drug release mechanisms, are also benefiting from AI. For instance, AI-assisted neural stimulators can detect abnormal nerve signals and trigger localized drug release to modulate neurological activity [141]. Similarly, AI-driven cardiovascular implants deliver anticoagulants or vasodilators in response to monitored hemodynamic changes [142]. These innovations highlight how AI-powered implantables contribute to precision therapy, minimizing systemic exposure and improving therapeutic outcomes [143].

6.7 Integration with Internet of Medical Things (IoMT)

The convergence of AI and the Internet of Medical Things (IoMT) has given rise to connected drug delivery ecosystems. IoMT devices continuously collect physiological data through sensors and transmit it to cloud-based AI platforms for analysis [144]. The AI algorithms process these data streams to make dosing recommendations, detect anomalies, or trigger automatic adjustments in delivery rate [145]. For example, AI-integrated smart pill systems can track ingestion events, monitor gastrointestinal conditions, and provide adherence feedback to clinicians [146]. The combination of wearable, implantable, and cloud-connected devices ensures continuous therapeutic optimization and enables remote healthcare management [147]. This digital transformation represents a key step toward the realization of autonomous precision therapeutics, where data, devices, and AI algorithms work synergistically to ensure optimal patient outcomes [148]. AI-enabled emerging technologies — from nanorobots and microchips to IoMT-driven implants — are redefining the future of drug delivery. By combining advanced sensors, predictive modeling, and autonomous control, these systems offer unparalleled accuracy, adaptability, and personalization in therapeutic management [149].

7: Applications of Artificial Intelligence in Controlled and Targeted Drug Delivery

The integration of Artificial Intelligence (AI) into controlled and targeted drug delivery systems represents one of the most impactful technological advancements in pharmaceutical science. Controlled drug delivery systems are designed to release therapeutic agents at a predetermined rate, location, and duration to achieve optimal pharmacological action with minimal side effects [150]. When combined with AI, these systems become intelligent platforms capable of adapting to physiological feedback and patient-specific data in real time [151]. AI algorithms can analyze biological and pharmacokinetic data to determine the most efficient delivery routes and dosing strategies. For instance, deep learning models can simulate how nanoparticles interact with biological membranes, predict drug diffusion profiles, and optimize particle size for enhanced bioavailability [152]. This predictive capacity accelerates formulation design and minimizes experimental workload [153].

7.1 AI in Nanoparticle-Based Drug Delivery

Nanoparticle-based drug delivery systems (NDDS) have gained immense popularity due to their ability to encapsulate drugs, improve solubility, and achieve targeted delivery. AI assists in optimizing formulation parameters such as particle size, zeta potential, drug loading, and release kinetics [154]. Machine learning (ML) algorithms analyze experimental datasets to correlate nanoparticle characteristics with in vivo pharmacokinetics and biodistribution profiles [155]. Neural network models can predict how nanocarriers respond to environmental stimuli such as pH, temperature, or enzymatic activity, facilitating the design of “smart” nanocarriers that release drugs in response to specific biological conditions [156]. Furthermore, AI-driven molecular simulations enable virtual screening of potential materials (e.g., lipids, polymers, dendrimers) for drug encapsulation efficiency and stability [157].

7.2 AI in Liposomal and Micellar Drug Delivery

Liposomes and micelles are classical examples of carrier systems that enhance the therapeutic index of drugs by reducing systemic toxicity and improving bioavailability [158]. AI models can predict the encapsulation efficiency, drug leakage rate, and stability of liposomal formulations by analyzing composition and preparation variables [159]. Genetic algorithms and Bayesian optimization are often employed to fine-tune lipid ratios, hydration times, and temperature conditions for optimal results [160]. Deep learning frameworks are also applied to predict pharmacokinetic behavior of liposomal drugs, including circulation time, clearance, and tissue distribution [161]. This approach enables virtual optimization before conducting costly and time-consuming animal studies [162].

7.3 AI in Implantable and Transdermal Drug Delivery Systems

Implantable and transdermal systems provide sustained drug release over extended durations, improving patient compliance and therapeutic outcomes [163]. AI enhances these technologies by enabling precise control over release kinetics and real-time monitoring. For example, reinforcement learning algorithms can be integrated with biosensors in implantable pumps to adjust drug infusion rates dynamically based on physiological responses [164]. In transdermal systems, AI-based image analysis assists in identifying optimal skin sites for drug permeation and predicting the effects of formulation components on skin barrier properties [165]. Furthermore, AI models can analyze micro-needle geometry and material parameters to improve drug penetration efficiency while minimizing discomfort [166].

7.4 AI-Driven Smart Drug Delivery Systems

The evolution of AI has given rise to smart drug delivery systems that integrate biosensors, data analytics, and feedback control mechanisms [167]. These systems can automatically detect changes in physiological parameters—such as glucose levels, pH, or temperature—and adjust drug release accordingly. Such adaptability is crucial for chronic diseases like diabetes, cancer, and cardiovascular disorders [168]. An example is the AI-integrated insulin pump, which uses continuous glucose monitoring data to predict blood sugar fluctuations and regulate insulin delivery [169]. Similarly, AI-enabled nanocarriers can sense the tumor microenvironment and release anticancer drugs selectively, thereby improving therapeutic efficacy while reducing systemic toxicity [170].

7.5 AI for Target Identification and Precision Drug Delivery

AI also facilitates precision drug targeting, which involves delivering therapeutic agents specifically to diseased cells or tissues while sparing healthy ones [171]. Machine learning models can analyze omics data (genomics, proteomics, metabolomics) to identify novel molecular targets [172]. Once identified, AI algorithms assist in designing drug carriers that can specifically recognize these targets through ligands, antibodies, or aptamers [173]. In oncology, for example, AI-driven image processing can identify tumor boundaries and vascular density, aiding in the design of targeted nanoparticles that home in on specific cancer cells [174]. This combination of imaging data with predictive modeling significantly enhances the accuracy of targeted drug delivery [175].

8: AI in Personalized and Adaptive Drug Delivery Systems

Personalized medicine represents a revolutionary approach in modern healthcare, focusing on tailoring therapeutic strategies to individual patient characteristics rather than adopting a one-size-fits-all model [176]. Artificial Intelligence (AI) plays a transformative role in realizing this concept by integrating patient-specific data such as genetics, metabolism, and environmental factors to design customized drug delivery systems [177]. The synergy between AI and personalized medicine enables precision dosing, improved therapeutic outcomes, and reduced adverse reactions [178].

8.1 Integration of Patient Data for Personalized Delivery

AI algorithms are capable of processing vast volumes of biomedical data, including genomic sequences, proteomic profiles, and clinical parameters [179]. Machine learning (ML) and deep learning (DL) models can analyze these datasets to predict patient responses to specific drugs, guiding the design of personalized delivery systems [180]. This approach helps in identifying optimal dosage regimens and delivery routes for individual patients, especially in complex diseases such as cancer, diabetes, and neurological disorders [181]. For example, in oncology, AI systems can assess tumor heterogeneity and predict drug resistance mechanisms, enabling oncologists to select personalized nanoformulations with targeted ligands [182]. Similarly, in diabetes management, AI models analyze glucose fluctuations and patient lifestyle data to determine the most effective insulin dosing pattern [183]. These applications significantly reduce the trial-and-error approach in therapy selection and dosage determination [184].

8.2 AI in Adaptive Drug Delivery Systems

Adaptive drug delivery systems utilize real-time feedback from patients to automatically adjust the rate and timing of drug release [185]. These systems often integrate biosensors and wearable technologies with AI algorithms to enable continuous monitoring of physiological parameters such as blood pressure, glucose levels, and heart rate [186]. Based on sensor data, AI-driven control models dynamically regulate drug release to maintain therapeutic concentrations within a safe and effective range [187]. Reinforcement learning (RL), a subset of AI, has shown promise in developing self-learning drug delivery systems capable of optimizing dosing schedules through continuous feedback [188]. In these systems, the AI algorithm learns from patient responses and environmental factors to improve decision-making over time, ensuring that treatment remains effective even as conditions change [189].

8.3 AI and Pharmacogenomics

Pharmacogenomics, the study of how genetic variations affect individual drug responses, is a key component of personalized medicine [190]. AI can analyze genetic data to identify mutations that influence drug metabolism, receptor binding, and toxicity profiles [191]. Using such insights, personalized drug delivery systems can be designed to bypass metabolic pathways associated with poor drug response or adverse effects [192]. For example, AI-based genomic models can predict whether a patient is a fast or slow metabolizer of specific drugs, allowing for customized release profiles or dose adjustments [193]. This integration of pharmacogenomic data with drug delivery design enhances therapeutic precision and patient safety [194].

8.4 AI in Personalized Cancer Therapy

In cancer therapy, interpatient variability often limits the effectiveness of standard treatments [195]. AI enhances personalized cancer drug delivery by analyzing multi-omics datasets—genomic, transcriptomic, and imaging data—to identify optimal drug combinations and delivery strategies [196]. Deep learning algorithms are used to model tumor growth dynamics, predict drug diffusion patterns within tumor tissues, and optimize nanoparticle design for improved tumor penetration [197].AI also facilitates real-time monitoring of treatment progress using imaging biomarkers. For example, machine learning algorithms can interpret MRI or PET scan data to assess tumor response and dynamically adjust drug delivery parameters [198]. This feedback-driven approach enhances treatment precision and reduces systemic toxicity [199].

8.5 AI in Predictive and Preventive Therapeutics

AI-powered predictive models can forecast disease progression and drug response patterns based on individual health profiles [200]. This capability enables the development of preventive drug delivery systems that initiate treatment before disease symptoms worsen [201]. For instance, in cardiovascular diseases, AI systems can analyze heart rate variability and blood pressure trends to predict potential hypertensive episodes and trigger the controlled release of antihypertensive drugs [202]. Similarly, wearable AI-integrated devices can continuously monitor biomarkers such as cortisol or cytokine levels to predict stress or inflammation-related conditions, adjusting drug delivery accordingly [203]. These preventive systems not only improve quality of life but also reduce healthcare costs by minimizing hospitalizations [204].

8.6 Challenges and Future Directions

While AI-driven personalized and adaptive drug delivery offers immense promise, several challenges remain. The integration of diverse data sources—genomic, clinical, and behavioral—requires standardized data formats and interoperable systems [205]. Ensuring data privacy and ethical handling of patient information is critical to gaining public trust [206]. Moreover, regulatory frameworks need to evolve to accommodate adaptive AI-driven systems that modify dosing in real time [207]. Future developments are expected to focus on hybrid AI models that combine mechanistic pharmacokinetic-pharmacodynamic (PK-PD) modeling with machine learning [208]. These integrated systems will provide a more comprehensive understanding of drug behavior in individuals and facilitate the development of fully autonomous, closed-loop drug delivery systems [209]. With continued advancements in biosensors, nanotechnology, and computational power, AI-based personalized medicine is poised to redefine the future of therapeutic care [210].

9: Role of AI in Pharmaceutical Manufacturing and Quality Control

Artificial Intelligence (AI) has emerged as a powerful enabler in the pharmaceutical manufacturing sector, enhancing the efficiency, precision, and reliability of drug production processes [211]. The complexity of modern drug delivery systems requires strict control over formulation parameters, production conditions, and product quality. AI provides advanced data analytics, predictive modeling, and automation capabilities that allow real-time monitoring and optimization of manufacturing workflows [212]. These innovations not only improve product quality but also reduce costs and accelerate time-to-market [213].

Image no 5

AI_in_Pharmaceutical_Manufacturing_and_Quality_Control_Chart.

9.1 AI in Process Optimization

Pharmaceutical manufacturing involves numerous critical steps such as mixing, granulation, drying, compression, coating, and packaging [214]. Each step is influenced by multiple variables that can affect the final product's quality and performance. AI algorithms, particularly machine learning (ML), are capable of analyzing complex datasets generated during manufacturing to identify optimal process conditions [215]. Neural networks and regression-based models can predict critical quality attributes (CQAs) such as particle size distribution, moisture content, and dissolution rate based on input variables like temperature, mixing time, and pressure [216]. This predictive ability enables real-time process adjustments, minimizing batch-to-batch variability and ensuring consistent quality [217].

9.2 AI and Quality by Design (QbD)

The concept of Quality by Design (QbD) emphasizes building quality into a product through systematic design rather than relying on end-product testing [218]. AI enhances QbD implementation by facilitating risk assessment, design space exploration, and multivariate data analysis [219]. Machine learning algorithms can simulate the impact of formulation and process variables on product performance, helping researchers define robust design spaces [220]. For instance, AI-driven predictive models can analyze thousands of formulation combinations virtually to determine the optimal composition for drug stability and release characteristics [221]. This approach accelerates formulation development while ensuring regulatory compliance [222].

9.3 AI in Process Analytical Technology (PAT)

Process Analytical Technology (PAT) is a framework used to monitor and control pharmaceutical manufacturing in real time [223]. AI significantly strengthens PAT by integrating advanced sensors, data analytics, and feedback control systems [224]. Through continuous data collection and analysis, AI models can detect process deviations early and suggest corrective actions before product quality is compromised [225]. Deep learning algorithms are particularly useful for processing spectral and imaging data from instruments like Near-Infrared (NIR) and Raman spectroscopy [226]. These models can identify subtle variations in raw materials or intermediate products that are often undetectable by traditional statistical methods [227].

9.4 AI in Predictive Maintenance and Equipment Monitoring

Equipment failure during manufacturing can lead to production delays and economic losses [228]. AI-based predictive maintenance systems analyze machine performance data—such as vibration, temperature, and power consumption—to predict potential breakdowns before they occur [229]. By employing time-series forecasting and anomaly detection algorithms, AI can alert operators to early signs of wear or malfunction, allowing maintenance to be performed proactively [230]. This reduces downtime, improves equipment lifespan, and ensures uninterrupted production [231].

9.5 AI in Supply Chain and Inventory Management

AI also extends its applications beyond production lines into pharmaceutical supply chain management [232]. Accurate demand forecasting, inventory optimization, and logistics management are critical to maintaining product availability and minimizing waste [233]. Machine learning models analyze market trends, seasonal variations, and real-time sales data to predict future demand with high accuracy [234]. This allows manufacturers to optimize production schedules and raw material procurement, preventing shortages or overproduction [235]. AI-powered blockchain systems further enhance supply chain transparency and traceability, ensuring product authenticity and reducing the risk of counterfeit drugs [236].

9.6 AI in Quality Assurance and Regulatory Compliance

Ensuring regulatory compliance is one of the most demanding aspects of pharmaceutical manufacturing [237]. AI supports quality assurance (QA) by automating documentation, audit trails, and deviation reporting [238]. Natural language processing (NLP) tools can analyze regulatory documents, extract key compliance requirements, and cross-verify them with internal data [239]. AI-based image recognition technologies are increasingly being used for visual inspection of tablets, capsules, and packaging materials to identify defects such as cracks, discoloration, or labeling errors [240]. These automated systems provide consistent, unbiased quality assessments and reduce human error [241]. Furthermore, regulatory authorities are gradually recognizing the potential of AI in ensuring data integrity and traceability [242]. The integration of AI with digital manufacturing platforms such as Pharma 4.0 facilitates seamless monitoring and documentation across all production stages, enhancing overall transparency and accountability [243].

9.7 Future Prospects of AI in Pharmaceutical Manufacturing

The future of pharmaceutical manufacturing lies in the integration of AI with other digital technologies such as robotics, the Internet of Things (IoT), and blockchain [244]. These interconnected systems enable the development of smart manufacturing facilities capable of autonomous decision-making and adaptive control [245]. AI-driven "digital twins" — virtual replicas of physical manufacturing systems — are emerging as valuable tools for process simulation, troubleshooting, and optimization [246]. These models allow manufacturers to test different scenarios virtually before applying them in real production, reducing risk and cost [247]. As AI technologies continue to mature, the pharmaceutical industry is expected to witness a paradigm shift from traditional, reactive production methods to predictive, data-driven, and autonomous manufacturing ecosystems [248]. Such transformation will enhance not only efficiency and quality but also sustainability and patient safety [249].

10: AI in Regulatory Affairs, Safety Assessment, and Ethical Considerations

The rapid adoption of Artificial Intelligence (AI) in pharmaceutical research, manufacturing, and drug delivery systems presents new opportunities and challenges for regulatory bodies worldwide [250]. While AI-driven innovations accelerate drug development and enhance therapeutic precision, they also demand updated frameworks to ensure patient safety, data integrity, and ethical compliance [251]. The intersection of AI with regulatory affairs and safety assessment is crucial to the responsible deployment of these technologies in the healthcare sector [252].

10.1 AI in Regulatory Affairs

Regulatory affairs play a vital role in ensuring that all pharmaceutical products meet established safety, efficacy, and quality standards [253]. The inclusion of AI in the development pipeline necessitates redefining regulatory procedures to address algorithm transparency, model validation, and continuous learning systems [254]. AI-based platforms can assist regulatory agencies in reviewing large volumes of preclinical and clinical data more efficiently [255]. Natural Language Processing (NLP) and text-mining tools automatically extract relevant information from submissions, enabling faster and more consistent assessments [256]. In addition, AI-driven analytics can detect inconsistencies or anomalies in datasets that might indicate experimental bias or data manipulation [257]. Regulatory organizations such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) are already exploring frameworks for evaluating AI-enabled medical products and digital health tools [258]. These frameworks emphasize the importance of algorithm interpretability, version control, and post-market performance monitoring [259].

10.2 AI in Drug Safety Assessment and Pharmacovigilance

AI technologies have revolutionized pharmacovigilance, the science of detecting, assessing, and preventing adverse drug reactions (ADRs) [260]. Traditional safety monitoring systems rely heavily on manual data entry and reporting, which can be slow and prone to underreporting [261]. AI systems, on the other hand, can automatically analyze massive datasets from clinical trials, electronic health records, and social media to identify potential safety signals in real time [262]. Machine learning algorithms can detect subtle correlations between patient demographics, dosage patterns, and adverse outcomes that are often overlooked by human analysts [263]. Deep learning models can also process unstructured data such as physician notes and patient narratives to provide comprehensive safety assessments [264]. For example, AI-based pharmacovigilance systems have been employed to monitor post-market drug performance, predicting the likelihood of adverse reactions before they escalate into public health concerns [265]. Moreover, predictive modeling helps pharmaceutical companies refine dosage forms, identify at-risk populations, and improve formulation safety profiles [266].

10.3 Ethical and Legal Considerations in AI-Driven Drug Delivery

Despite its potential, the integration of AI into healthcare introduces numerous ethical and legal challenges [267]. One of the major concerns involves data privacy and patient consent. AI systems depend on large-scale data collection from patients, which may include sensitive medical, genetic, and behavioral information [268]. Ensuring secure data storage and compliance with privacy regulations such as the General Data Protection Regulation (GDPR) and Health Insurance Portability and Accountability Act (HIPAA) is critical [269]. Another ethical issue is algorithmic bias, where AI systems may inadvertently reproduce or amplify existing disparities in healthcare outcomes [270]. This bias can arise from skewed training datasets or inadequate representation of minority populations [271]. Regulatory authorities and developers must collaborate to ensure fairness, transparency, and accountability in AI models used for drug delivery and treatment decisions [272]. Additionally, questions of liability arise when AI-based systems make autonomous decisions. Determining accountability for errors—whether from the developer, manufacturer, or healthcare provider—remains an unresolved legal challenge [273]. This ambiguity underscores the need for clear guidelines on AI system validation, risk assessment, and post-market surveillance [274].

10.4 AI Governance and Policy Development

To support the ethical integration of AI in pharmaceuticals, robust governance frameworks are required [275]. Governments and international organizations are developing policies to promote innovation while maintaining public safety [276]. The World Health Organization (WHO) and the International Medical Device Regulators Forum (IMDRF) have emphasized the importance of establishing global standards for AI validation and regulatory oversight [277]. These policies advocate for the explainability of AI systems—ensuring that their decision-making processes are understandable to human experts [278]. Transparency in data use, algorithm development, and performance metrics fosters trust among regulators, clinicians, and patients [279]. The adoption of AI ethics boards within pharmaceutical companies can further ensure adherence to moral and regulatory standards. These boards oversee AI-based projects to evaluate ethical risks, data governance, and compliance with international regulations [280].

10.5 The Path Toward Trustworthy and Transparent AI

Building public and institutional trust in AI is essential for its widespread adoption in drug delivery and healthcare [281]. Achieving this requires continuous collaboration among scientists, regulatory bodies, clinicians, and ethicists [282]. Transparent data practices, open-source algorithm sharing, and stakeholder engagement can help establish a responsible AI ecosystem [283]. The future regulatory landscape will likely shift toward dynamic oversight models, where AI systems are continuously monitored and updated throughout their lifecycle [284]. This approach will allow regulators to track algorithm performance, ensure model validity, and respond to new data patterns in real time [285]. Ultimately, the goal is to create an AI framework that balances innovation with responsibility—facilitating safer, faster, and more effective drug delivery while protecting patient rights and societal values [286].

Image no:6

11: Integration of AI with Emerging Technologies in Drug Delivery (Nanotechnology, IoT, Robotics, and 3D Printing)

The convergence of Artificial Intelligence (AI) with emerging technologies such as nanotechnology, the Internet of Things (IoT), robotics, and 3D printing represents a new frontier in pharmaceutical innovation [287]. This interdisciplinary integration enables the creation of intelligent, responsive, and patient-centered drug delivery systems that go beyond conventional formulations [288]. By combining AI's predictive and analytical power with advanced material science and digital manufacturing, pharmaceutical researchers can design precise, efficient, and adaptive delivery platforms [289].

11.1 AI and Nanotechnology in Drug Delivery

Nanotechnology has transformed drug delivery by enabling precise targeting, improved solubility, and controlled release of therapeutic agents [290]. The addition of AI amplifies these benefits by optimizing nanoparticle design parameters such as particle size, surface charge, and composition [291]. Machine learning algorithms analyze large experimental datasets to predict nanoparticle behavior under physiological conditions, such as drug release rate and biodistribution [292]. AI-based molecular modeling assists in screening nanocarrier materials (e.g., lipids, polymers, dendrimers, and metal oxides) for stability, biocompatibility, and target specificity [293]. In oncology, AI-enhanced nanocarriers are used to identify tumor markers and deliver drugs selectively to malignant tissues [294]. These systems can be programmed to respond to microenvironmental triggers like pH, temperature, or enzyme concentration, achieving site-specific drug release with minimal toxicity [295]. The combination of AI and nanotechnology thus accelerates the development of "smart nanomedicines" with adaptive therapeutic behavior [296].

11.2 AI and the Internet of Things (IoT)

The integration of AI with the Internet of Things (IoT) has opened new avenues for connected healthcare and real-time drug delivery monitoring [297]. IoT devices—such as wearable sensors, implantable chips, and smart packaging—collect continuous physiological and environmental data from patients [298]. AI algorithms process this data to personalize drug administration schedules and adjust dosage dynamically [299]. For example, AI-enabled IoT systems are being developed for diabetic patients to synchronize continuous glucose monitoring devices with insulin pumps, optimizing dosage in real time [300]. Similarly, AI-IoT combinations in cardiovascular therapy enable continuous monitoring of heart rate, blood pressure, and medication adherence [301]. Smart pill technologies equipped with ingestible sensors can record patient compliance and transmit data to healthcare providers through secure cloud systems [302]. AI then interprets this data to identify adherence patterns and suggest personalized interventions [303]. This seamless integration promotes proactive healthcare and enhances treatment outcomes [304].

11.3 AI and Robotics in Pharmaceutical Applications

Robotics combined with AI is revolutionizing pharmaceutical manufacturing, compounding, and precision drug delivery [305]. AI-guided robotic systems are used for automated formulation screening, high-throughput experimentation, and microscale synthesis [306]. These technologies enhance reproducibility, minimize human error, and reduce development timelines [307]. In clinical applications, AI-assisted microrobots—often designed at the nanoscale—are being developed for site-specific drug transport [308]. These microrobots can navigate through biological fluids, cross physiological barriers, and release drugs directly at the target site under magnetic or chemical guidance [309]. For instance, AI-controlled magnetic nanorobots are being explored for targeted chemotherapy, where they deliver cytotoxic drugs directly to tumor sites while avoiding healthy tissues [310]. Reinforcement learning algorithms optimize navigation routes and drug release timing, ensuring maximum efficacy with minimal invasiveness [311]. Additionally, robotic systems integrated with AI are utilized in surgical drug delivery, implant placement, and controlled infusion systems, offering precision beyond human capability [312].

11.4 AI and 3D Printing in Drug Delivery

Three-dimensional (3D) printing, also known as additive manufacturing, enables the fabrication of personalized drug delivery devices and dosage forms with complex geometries [313]. AI enhances this technology by predicting optimal formulation parameters, print settings, and material combinations to achieve desired drug release profiles [314]. Machine learning algorithms can analyze factors such as polymer viscosity, nozzle temperature, and layer thickness to optimize printability and mechanical strength [315]. AI-driven simulations also allow virtual prototyping of 3D-printed tablets, minimizing material wastage and accelerating product development [316]. For instance, AI-optimized 3D printing techniques have been used to create multi-drug polypills, transdermal patches, and implantable systems that provide customized release kinetics tailored to individual patients [317]. These systems not only improve therapeutic precision but also support the goals of personalized medicine [318]. Furthermore, AI-integrated 3D bioprinting is being explored for creating tissue-engineered scaffolds that can release growth factors or therapeutic agents in response to biological cues [319]. This synergy holds promise for regenerative medicine and localized drug therapy [320].

11.5 Future Outlook: Convergence of AI and Emerging Technologies

The future of pharmaceutical innovation lies in the convergence of AI with nanotechnology, IoT, robotics, and 3D printing to develop cyber-physical drug delivery ecosystems [321]. In such systems, AI acts as the “central intelligence,” analyzing continuous feedback from biosensors, nanocarriers, and patient data streams to make autonomous therapeutic decisions [322]. Hybrid AI models combining mechanistic simulations and real-world data analytics will enable dynamic control over complex delivery systems [323]. For example, an AI-driven nanorobot could detect molecular changes in tissue, communicate with a wearable IoT sensor, and trigger a 3D-printed implant to release additional doses as needed [324]. While these integrated systems hold immense potential, challenges remain regarding interoperability, data security, regulatory validation, and cost-effectiveness [325]. Addressing these challenges through collaborative research and global policy alignment will be key to transforming AI-enabled smart therapeutics into clinical reality [326].

12. Applications of AI in Controlled and Targeted Drug Delivery

Controlled and targeted drug delivery systems represent one of the most significant areas where Artificial Intelligence (AI) has shown immense potential. The goal of such systems is to deliver therapeutic agents precisely to the site of action at the desired rate and duration, thereby maximizing therapeutic benefits and minimizing systemic toxicity. AI technologies have contributed to various aspects of this field, ranging from the design of carrier systems to the prediction of drug release kinetics and optimization of targeting strategies.

1. AI in Nanocarrier Design

Nanocarriers such as liposomes, dendrimers, and polymeric nanoparticles are widely used for targeted drug delivery. Designing these carriers requires careful selection of materials, particle size, surface charge, and drug-to-carrier ratio to achieve the desired pharmacokinetic and pharmacodynamic outcomes. AI algorithms, especially machine learning (ML) and deep learning (DL) models, are being increasingly used to optimize nanocarrier formulations. These models analyze complex datasets involving multiple physicochemical and biological parameters to predict optimal formulations with improved drug encapsulation efficiency, stability, and release behavior. For instance, ML models have been employed to predict nanoparticle size and polydispersity index based on formulation parameters, enabling faster and more efficient design processes without extensive experimental trials [243–249].

2. Targeting Efficiency and Biodistribution

3. AI also plays a critical role in predicting and optimizing the biodistribution of nanocarriers within the body. Computational modeling and AI-driven simulations can evaluate how nanoparticles interact with biological barriers such as the blood-brain barrier or tumor microenvironment. Deep neural networks are capable of identifying relationships between particle properties and targeting efficiency, assisting in the design of systems with improved tissue-specific delivery. Reinforcement learning models can further simulate drug transport pathways and help determine the most effective targeting ligands for receptor-mediated delivery [250–256].

4. AI-Driven Controlled Release Modeling

Controlled release drug delivery requires a detailed understanding of drug diffusion, degradation, and polymer erosion mechanisms. Traditional models often fail to accurately predict release kinetics due to the complexity of these processes. AI-based predictive models, such as artificial neural networks (ANNs) and support vector machines (SVMs), have demonstrated superior performance in modeling non-linear relationships between formulation components and release rates. By training on experimental data, these models can forecast release profiles under various physiological conditions, thus enabling the design of smart delivery systems with predetermined release characteristics [257–263].

5. Smart Implants and Biosensor-Integrated Systems

Recent advancements have introduced AI-enabled implants and biosensor-integrated drug delivery systems capable of real-time monitoring and automated control of drug release. These intelligent systems combine physiological feedback with AI algorithms to adjust dosing in response to patient-specific needs. For example, closed-loop insulin pumps use AI to monitor glucose levels continuously and modulate insulin delivery automatically. Similar systems are being developed for pain management, hormonal therapies, and chemotherapy, where precise control over dosing can significantly enhance therapeutic outcomes and patient safety [264–270].

6. AI in Predicting Pharmacokinetics and Pharmacodynamics

AI tools are increasingly utilized to predict pharmacokinetic (PK) and pharmacodynamic (PD) profiles in targeted drug delivery. By integrating patient-specific parameters such as age, weight, genetic background, and disease state, AI models can estimate drug absorption, distribution, metabolism, and excretion patterns with high accuracy. These insights guide the selection of delivery routes, dosing regimens, and carrier designs that optimize therapeutic efficiency while minimizing adverse effects [271–277].

7. AI in Tumor-Targeted and CNS Drug Delivery

One of the most challenging areas of drug delivery is targeting drugs to the brain and tumor tissues due to the presence of physiological barriers. AI has facilitated the development of targeted delivery strategies by analyzing molecular descriptors, permeability characteristics, and receptor expression patterns. Predictive modeling allows researchers to identify compounds and carrier systems with higher penetration capabilities across barriers such as the blood-brain barrier (BBB). Similarly, AI-guided drug delivery in oncology utilizes image-based algorithms to predict tumor heterogeneity and drug accumulation, thus enabling personalized therapeutic regimens [278–285].

FUTURE PERSPECTIVES

The application of AI in controlled and targeted drug delivery is expected to expand significantly with advancements in computational power, data integration, and multi-omics technologies. Future AI systems will likely combine predictive modeling, bioinformatics, and real-time feedback mechanisms to create adaptive drug delivery systems capable of autonomous decision-making. These intelligent systems will not only enhance therapeutic precision but also contribute to the broader field of personalized and preventive medicine.

CONCLUSION

The integration of Artificial Intelligence (AI) into drug delivery systems has redefined the future of pharmaceutical sciences. It has enabled a shift from conventional, trial-and-error–based formulation development toward intelligent, data-driven, and patient-specific approaches. AI-driven tools, including machine learning, neural networks, and predictive algorithms, have shown the capability to analyze vast and complex datasets, optimize formulation parameters, and predict drug release profiles with remarkable precision. Through these advancements, researchers and pharmaceutical industries have achieved higher efficiency in the design of targeted, controlled, and personalized drug delivery systems. AI has facilitated the discovery of novel carriers, improved bioavailability, and enhanced therapeutic outcomes while minimizing adverse effects. Its applications span across nanotechnology-based systems, 3D-printed dosage forms, implantable devices, and smart transdermal patches, all contributing to a more adaptive and responsive healthcare model. Furthermore, AI plays a crucial role in bridging preclinical and clinical research by modeling pharmacokinetic and pharmacodynamic behaviors, reducing experimental time, and supporting regulatory decision-making. The automation and digitization enabled by AI contribute to faster drug development, cost reduction, and improved reproducibility in formulation science. However, the adoption of AI in pharmaceutical technology is not without challenges. Issues such as data privacy, algorithmic transparency, ethical compliance, and standardization must be carefully addressed to ensure reliability and clinical safety. Collaboration among researchers, clinicians, data scientists, and regulatory authorities is essential for translating AI-based innovations into practical and accepted therapeutic solutions. Looking ahead, the convergence of AI with other emerging technologies such as the Internet of Medical Things (IoMT), quantum computing, and robotics promises a new era of intelligent and adaptive drug delivery. These integrated systems will not only optimize therapeutic efficiency but also support real-time patient monitoring and precision dosing, thereby transforming healthcare into a more predictive and preventive model. In conclusion, Artificial Intelligence is no longer a futuristic concept but a foundational element in modern drug delivery. It represents the dawn of a new paradigm in pharmaceutical development—one that emphasizes intelligence, efficiency, personalization, and global accessibility. With continued research and responsible implementation, AI will undoubtedly lead the transformation of drug delivery into a smarter, safer, and more patient-centered discipline.

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