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Research Article

Artificial Intelligence-Driven Design and Optimization of Advanced Drug Delivery Systems: From Formulation Prediction to Clinical Translation: A Comprehensive Review

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Abstract

Advanced drug delivery systems (DDS) — including polymeric and lipid nanoparticles, lipid nanoparticles (LNPs) for nucleic acid therapeutics, solid oral dosage forms, and three-dimensional (3D)-printed and stimuli-responsive platforms — require the simultaneous optimization of dozens of interacting formulation and process variables to achieve target size, drug loading, release kinetics, stability, and biological performance. Traditional design-of-experiments and trial-and-error approaches struggle to navigate this high-dimensional, nonlinear design space efficiently. Artificial intelligence (AI) and machine learning (ML) — spanning classical regression and ensemble methods, deep neural networks, graph neural networks, generative models, and Bayesian optimization — are increasingly used to predict critical quality attributes, accelerate excipient and lipid screening, optimize manufacturing processes, and guide the transition of novel delivery systems from bench to clinic. This review synthesizes recent literature on AI-driven formulation prediction across nanoparticulate, lipid-based, oral solid, and 3D-printed dosage forms; AI-guided process optimization and digital-twin-enabled manufacturing; and the evolving regulatory landscape for AI in pharmaceutical development, including the U.S. Food and Drug Administration's 2025 draft guidance on AI in regulatory decision-making. We also discuss persistent barriers to translation — data scarcity and quality, model interpretability, cross-laboratory generalizability, and validation standards — and outline emerging directions, including self-driving laboratories, federated learning, digital patient twins, and large language model-assisted formulation design, that may further shorten the path from AI-predicted formulation to clinically approved product.

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1. INTRODUCTION

The design of an advanced drug delivery system is fundamentally a multi-objective optimization problem. A single nanoparticle formulation, for example, is defined by drug and excipient identity, component ratios, solvent system, and process parameters such as flow rate, temperature, and mixing energy, all of which jointly determine particle size, polydispersity, surface charge, encapsulation efficiency, and drug release kinetics.[1,3] The number of plausible formulations that could in principle be tested for a single lipid nanoparticle (LNP) system alone has been estimated at roughly ten billion combinations once ionizable lipid structure, helper lipid, PEG-lipid, cholesterol, and their molar ratios are all varied,[26] a search space that is far beyond the reach of conventional design-of-experiments (DoE) or one-factor-at-a-time screening.

Artificial intelligence and machine learning offer a complementary paradigm: rather than exhaustively testing formulations, models are trained on existing experimental data to learn the mapping between formulation/process inputs and critical quality attributes (CQAs), and are then used to predict, rank, or generate new candidate formulations before they are synthesized.[1,5,9] Over the past five years, this approach has expanded from simple regression-based quantitative structure-property relationships (QSPR) toward deep learning, graph neural networks, generative adversarial networks (GANs), reinforcement learning, and Bayesian optimization applied across essentially every major delivery modality — polymeric and lipid nanoparticles, liposomes, solid lipid nanoparticles, nanostructured lipid carriers, nanoemulsions, self-emulsifying systems, solid oral dosage forms, long-acting injectables, and 3D-printed personalized medicines.[3,4,5,7]

This review provides an integrated overview of how AI is being applied across the drug delivery development pipeline: from in silico formulation prediction and rational excipient/lipid design, through AI-guided process optimization and digital-twin-enabled manufacturing, to the practical and regulatory considerations that govern clinical translation. We close by discussing the principal limitations of current AI approaches in this field and the directions likely to shape the next generation of AI-designed delivery systems.

2. The AI/ML Toolbox for Drug Delivery Science

A useful way to organize the diverse AI methods used in drug delivery research is by the type of task they perform: prediction, generation, and optimization.

2.1 Predictive modeling

Supervised ML algorithms — random forests, support vector machines, gradient-boosted trees (XGBoost, LightGBM), and artificial neural networks (ANNs) — are trained on historical formulation datasets to predict CQAs such as particle size, encapsulation efficiency, zeta potential, and release profile from formulation and process inputs.[5,9,21] Platforms such as FormulationAI have compared more than ten algorithm families for nanoparticle property prediction and consistently found tree-ensemble methods (random forest, LightGBM, XGBoost) among the strongest performers for tabular formulation data.[10] Deep neural networks (DNNs) extend this approach to higher-dimensional or structured inputs, such as predicting nanoparticle biodistribution (e.g., liver/spleen accumulation) directly from protein-corona adsorption profiles.[10]

2.2 Generative and structure-based design

Where predictive models rank existing candidates, generative approaches propose new ones. Recurrent neural networks, variational autoencoders, GANs, and transformer-based architectures have been used to generate novel excipient, polymer, and ionizable lipid structures with desired physicochemical properties, and graph neural networks (GNNs) are increasingly applied because molecules and nanoparticle assemblies are naturally represented as graphs.[10,11,13] Protein structure-prediction tools such as AlphaFold and AlphaFold2 are also being incorporated into nanomedicine design pipelines to predict the structure of peptide- or protein-based targeting ligands used on nanocarrier surfaces.[10]

2.3 Optimization and active learning

Bayesian optimization (BO) and related surrogate-modeling, active-learning strategies are particularly well suited to formulation development because they are designed to find good solutions with very few experiments — a critical advantage when each experimental data point is costly to generate.[3,4] In one reported comparison for solid oral dosage form optimization, a Bayesian optimization workflow reached an optimal formulation in approximately ten experiments, compared with twenty-five required by a conventional design-of-experiments strategy, and it outperformed both random search and traditional optimization approaches.[3] These workflows are also central to the emerging concept of self-driving or autonomous laboratories, in which an AI agent proposes the next experiment, a robotic platform executes it, and the resulting data are fed back to update the model in a closed loop.[3,4]

2.4 Digital twins and process models

At the manufacturing level, digital twins — dynamic, data-driven virtual replicas of a physical unit operation or production line — combine mechanistic process models with real-time sensor data and machine learning to enable predictive process control, real-time release testing, and rapid what-if scenario analysis.[29,30,31] These sit within the broader Pharma 4.0 movement, which couples process analytical technology (PAT), the Internet of Things, and advanced data analytics to move continuous pharmaceutical manufacturing toward greater automation.[29,31]

3. AI-Driven Formulation Prediction

3.1 Polymeric and lipid nanoparticles

Nanoparticulate drug delivery systems (NDDS) — polymeric nanoparticles, liposomes, solid lipid nanoparticles,

nanostructured lipid carriers, nanoemulsions, nanosuspensions, niosomes, and lipid-polymer hybrids — now include more than ninety approved nanomedicines, yet their development remains hampered by the complexity of jointly optimizing formulation composition and manufacturing process.[5] ML models trained on historical formulation datasets are used to predict particle size, surface charge, drug encapsulation and loading efficiency, release behavior, and colloidal stability directly from excipient identity and process parameters, substantially narrowing the experimental space that must be tested empirically.[2,5,12] Case studies have also shown that supervised models can forecast nanoparticle behavior in biological environments — for example, protein-corona formation and subsequent organ accumulation — which is important for anticipating off-target effects and improving tissue-targeting design before animal studies begin.[2,10]

A recent head-to-head evaluation compared purpose-built ML models against general-purpose generative AI chatbots (ChatGPT, Gemini, DeepSeek) prompted to suggest lipid-based or PLGA nanoparticle formulations targeting a defined particle size; the purpose-trained ML models substantially outperformed the general chatbots, underscoring that domain-specific training data remain essential even as large language models become more capable.[12]

3.2 Lipid nanoparticles for nucleic acid delivery

The clinical success of LNP-delivered mRNA vaccines has made ionizable lipid design one of the most active areas of AI-guided formulation research. Conventional LNP optimization screens the four canonical components — ionizable lipid, helper lipid, PEG-lipid, and cholesterol — largely by trial and error, a process that is slow and costly given the combinatorial size of the design space.[26,36] Machine learning models, including random forest and gradient-boosted tree regressors, have been trained on libraries of LNP formulations to predict in vivo transfection or antibody titer outcomes directly from lipid structure and composition; one such LightGBM-based model, trained on 325 mRNA-LNP formulations, achieved strong predictive performance ($R^2 > 0.87$) and correctly identified which ionizable-lipid substructures were most associated with immunogenicity, findings that were subsequently corroborated in mouse studies comparing the clinically used lipids MC3 and SM-102.[27]

More recent work has moved from prediction toward generative design: an AI-driven virtual screening pipeline evaluated nearly twenty million candidate ionizable lipid structures across two rounds of generation and screening to predict apparent pKa and mRNA delivery efficiency, ultimately nominating a small set of novel lipid candidates for synthesis and testing.[11] Other groups have applied random forest regression trained on more than 300 molecular and formulation features across a panel of LNPs to predict mRNA expression efficiency, supporting rational rather than purely empirical lipid selection.[28]

3.3 Solid oral dosage forms

For tablets, capsules, and other solid oral dosage forms, AI/ML methods are used to predict dissolution and release profiles, guide excipient and polymer selection, and support quality-by-design (QbD) formulation strategies, complementing rather than replacing pharmaceutical scientists' judgment.[6,9] As noted above, Bayesian optimization workflows have demonstrated marked efficiency gains over classical DoE approaches for immediate-release solid oral formulations, reducing the number of experiments required to reach an optimal formulation.[3]

3.4 3D-printed and personalized dosage forms

Pharmaceutical 3D printing (3DP) is a natural fit for AI integration because the fabrication process is already fully digitized, making it straightforward to couple design parameters directly to machine learning models.[14,16] ANNs and other ML models have been used to predict suitable print geometries — for example, surface-area-to-volume ratios of 3D-printed tablets — needed to achieve a desired dose and release profile, reducing the need for iterative physical prototyping.[20] GANs have also been proposed for generating novel 3D-printed dosage-form geometries and predicting resulting drug release curves; in one reported comparison, an ML-based prediction of dissolution behavior achieved an f2 similarity score of 90.9 against experimental data, versus 57.5 for a conventional partial least squares method, with the FDA's threshold for acceptable similarity between predicted and true dissolution profiles set at 50.[14]

AI is also being applied downstream of formulation design, to in-line quality control of 3D-printed medicines. Machine-vision systems trained on synthetic, photorealistic images of 3D-printed dosage forms have been used to classify print quality without the cost and time of building large real-image training sets, illustrating how AI can support both the design and the manufacturing-quality-control ends of personalized 3DP medicine.[18] Coupled with decentralized, point-of-care manufacturing concepts now under discussion with medicines regulators, AI-guided 3DP is positioned as a route toward truly individualized dosage forms tailored to a patient's dose, release profile, and swallowing or administration needs.[17,19]

4. AI-Guided Process Optimization and Manufacturing

4.1 Bayesian optimization and self-driving experimentation

Beyond formulation composition, AI is increasingly applied to the manufacturing process itself — mixing, granulation, extrusion, spray-drying, microfluidic nanoprecipitation, and lyophilization — where process parameters interact nonlinearly with formulation variables to determine final product quality. Surrogate modeling and active learning allow an optimization algorithm to select the next most informative experiment, closing the loop between model and laboratory and enabling formulation and process co-optimization with a fraction of the experimental burden required by conventional approaches.[3,4]

4.2 Digital twins and Pharma 4.0

Digital twins pair a physical manufacturing asset or production line with a continuously updated virtual model, allowing real-time monitoring, predictive maintenance, and rapid in silico testing of process changes before they are implemented on the plant floor.[29,30,31] Within continuous pharmaceutical manufacturing specifically, digital-twin frameworks have been developed that ingest real-time process data to update model parameters and flag process settings likely to produce out-of-specification product, supporting corrective action before a batch is compromised.[43,44] Applications reported to date span small-molecule active pharmaceutical ingredient (API) synthesis and crystallization through to end-to-end continuous drug-product manufacturing, and are explicitly framed by regulators and industry as operating within a risk-based quality framework (e.g., ICH Q9) rather than replacing existing quality systems.[48,49]

4.3 Machine vision and automated quality control

Machine vision — a specific application of deep learning to image data — is being deployed for automated visual inspection of dosage forms, replacing or augmenting manual inspection with faster, more consistent classification of defects or dimensional variation, including for 3D-printed products where geometry itself is a therapeutically relevant variable.[18]

5. From Bench to Bedside: Clinical Translation

5.1 Predicting biological performance and PK/PD

A formulation that meets its in vitro CQA targets does not automatically perform as intended in vivo. AI and ML are therefore also applied to bridge formulation science and pharmacology — predicting pharmacokinetic and pharmacodynamic (PK/PD) behavior, toxicity, and biodistribution from formulation and molecular features, and supporting the design of long-acting injectable and implantable systems where in vivo release kinetics are difficult to predict from in vitro release testing alone.[1,9,10] Personalized-medicine applications extend this further, using AI models trained on real-world patient, genomic, and phenotypic data to inform individualized dosing and formulation choices.[1,9]

5.2 Barriers to translation

Despite these advances, most published AI/ML formulation models remain decision-support tools operating alongside expert formulators rather than autonomous systems, reflecting the current limits of biological complexity, data availability, and model validation. [6,13] Commonly cited translational barriers include:

- Data quality and scarcity — many published formulation datasets are small, heterogeneous across laboratories and instruments, and inconsistently reported, which limits model generalizability. [2,5]
- Algorithm transparency and interpretability — complex models such as deep neural networks and GANs can be difficult to interpret mechanistically, which complicates both scientific understanding and regulatory review.[2,13]
- Biological complexity — in vitro-trained models often struggle to fully capture the biological barriers (protein corona formation, immune clearance, tissue-specific transport) that determine in vivo performance. [6,13]
- Cross-site and cross-scale generalizability — models trained at bench scale on a specific instrument or process do not automatically transfer to pilot or commercial manufacturing scale. [3,29]

5.3 Regulatory landscape

Regulatory clarity is a precondition for routine clinical translation of AI-designed delivery systems. In January 2025, the U.S. Food and Drug Administration issued its first draft guidance specifically addressing AI in drug and biological product development, titled Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products.[21,22] The draft guidance introduces a risk-based framework organized around the AI model's specific "context of use" (COU) and outlines a seven-step process for establishing model credibility: sponsors are expected to define the decision the model will inform, delineate its context of use, assess model risk, and generate validation evidence proportionate to that risk.[23,24] Notably, the guidance explicitly excludes AI used purely in early drug discovery and AI used for internal operational efficiency (e.g., drafting regulatory documents) that does not affect patient safety, drug quality, or the reliability of results — the guidance's scope is limited to AI whose outputs directly inform a regulatory decision about safety, effectiveness, or quality.[23] The FDA has since published companion, non-binding "Guiding Principles of Good AI Practice in Drug Development" resources, and the agency's Center for Drug Evaluation and Research (CDER) has stated that it seeks to ensure drugs remain safe and effective while facilitating continued innovation in AI-enabled development.[27] Public comments on the January 2025 draft guidance closed in April 2025, and as of this writing the guidance remains in draft form, alongside a parallel regulatory track for AI/ML-enabled medical devices (Software as a Medical Device and predetermined change control plans) administered by FDA's Center for Devices and Radiological Health.[25]

6. Challenges and Limitations

Several cross-cutting challenges temper enthusiasm for AI in drug delivery design and warrant explicit consideration by both formulation scientists and regulators.

- Reproducibility and dataset bias: much of the published training data derives from academic laboratories using heterogeneous protocols, raising the risk that models learn laboratory-specific artifacts rather than generalizable structure-property relationships. [2,5]
- Model interpretability versus performance trade-offs: the most predictive models (deep neural networks, ensemble methods) are often the least interpretable, complicating mechanistic insight and regulatory trust. [2,13]

- Validation standards: unlike computational fluid dynamics or PK modeling, there is not yet a widely agreed standard for how much experimental validation an ML-predicted formulation requires before progressing to preclinical testing.[6]
- Data and intellectual property sharing: because formulation datasets are commercially sensitive, cross-company or public data sharing — which would otherwise improve model generalizability — remains limited. [2,7]
- Workforce and integration: effective use of AI/ML tools requires formulation scientists with cross-disciplinary data science literacy, and current guidance continues to position AI as a decision-support layer rather than an autonomous formulator.[6]

7. Future Perspectives

Several developments are likely to further accelerate the integration of AI across the drug delivery pipeline. Self-driving laboratories that close the loop between Bayesian optimization algorithms and robotic experimentation are expected to expand from small-molecule formulation into more complex modalities such as LNPs and biologics.[3,4] Digital-twin frameworks are moving from unit-operation-level models toward end-to-end, plant-wide representations of continuous manufacturing processes, and are being extended conceptually toward "digital patient twins" that simulate patient-specific formulation response to support personalized dosing and clinical trial design.[29,49] Generative and graph-based deep learning methods are expanding beyond ionizable lipid design toward de novo design of polymers, excipients, and targeting ligands, often integrated with protein-structure prediction tools.[10,11] Finally, large language models are beginning to be evaluated as formulation-design assistants, though current evidence indicates that purpose-built, domain-trained ML models still outperform general-purpose generative AI chatbots on quantitative formulation prediction tasks, suggesting that near-term gains will come from combining LLM-based literature synthesis and hypothesis generation with specialized predictive and generative models rather than from LLMs replacing them.[12]

8. CONCLUSION

Artificial intelligence and machine learning have moved from a peripheral computational curiosity to an increasingly standard component of the drug delivery development toolkit, spanning formulation property prediction, generative design of nanocarriers and lipids, process optimization through Bayesian and active-learning methods, and digital-twin-enabled manufacturing. The clinical impact of these tools is already visible in LNP-based mRNA vaccines and is expanding into oral solid dosage forms, long-acting injectables, and personalized 3D-printed medicines. Realizing the full potential of AI-driven drug delivery design will depend on addressing persistent challenges around data quality, model interpretability, and cross-scale validation, and on the continued maturation of regulatory frameworks such as the FDA's 2025 draft AI guidance, which together will determine how quickly AI-predicted formulations move from the laboratory to the clinic.

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