

Pharmaceutical Applications of Artificial Intelligence in Drug Formulation, Development, and Personalized Pharmacy Practice

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ABSTRACT

Objective: To evaluate the effectiveness of a structured training manual in strengthening women's reproductive health capacity among Self-Help Group (SHG) members in selected talukas of Sangli District, Maharashtra, India.

Methods: A mixed-method evaluative study was conducted among 200 women belonging to selected SHGs. Quantitative data were collected using structured instruments assessing reproductive health knowledge, attitude and self-reported practices at baseline, day 15, day 30 and day 60 following implementation of a structured training manual. The manual was developed from literature, reproductive health guidance, government programmes, expert consultation and community needs, and was prepared in Marathi using simple language and illustrations. Repeated-measures analysis of variance with Bonferroni-adjusted pairwise comparisons was used to examine changes over time. Qualitative data were obtained through three focus group discussions involving 21 SHG members and were analysed thematically.

Results: Baseline mean scores were 17.84±4.36 for knowledge, 49.28±7.12 for attitude and 20.62±5.08 for self-reported practice. Overall capacity-building increased from 87.74±11.84 at baseline to 102.24±10.28, 113.94±9.18 and 121.38±8.42 on days 15, 30 and 60, respectively. Repeated-measures ANOVA showed significant improvements in knowledge (F=412.86; p<0.001), attitude (F=328.41; p<0.001), practice (F=376.95; p<0.001) and overall capacity-building scores (F=495.27; p<0.001). Qualitative findings indicated increased awareness, confidence, communication, and adoption of healthier reproductive health practices.

Conclusion: The structured training manual was associated with significant and sustained improvement in reproductive health knowledge, attitude, self-reported practices and overall capacity among SHG members. SHGs may provide a feasible community platform for reproductive health capacity-building interventions.

Keywords: Women's Health; Reproductive Health; Self-Help Groups; Health Education; Health Knowledge, Attitudes, Practice; Community Health Nursing.

1. INTRODUCTION

Artificial intelligence (AI) has moved from a predominantly experimental computational discipline toward a practical enabling technology for biomedical research and healthcare. In the pharmaceutical sector, AI encompasses machine learning (ML), deep learning (DL), natural language processing (NLP), computer vision, reinforcement learning, generative models, and related analytical methods. These approaches can learn relationships from structured and unstructured data and generate predictions, classifications, recommendations, or optimized experimental choices. Current regulatory thinking emphasizes that the usefulness of AI depends not only on predictive performance but also on a clearly defined context of use, data governance, risk management, and lifecycle oversight.¹⁻³

Pharmaceutical development is particularly suitable for AI because it generates heterogeneous datasets spanning molecular structures, physicochemical properties, formulation compositions, manufacturing parameters, analytical measurements, clinical observations, and post-market safety reports. AI can therefore connect information that is often analyzed separately. In drug discovery, models may prioritize targets and candidate molecules; in formulation, they may map composition and process variables to critical quality attributes (CQAs); and in pharmacy practice, they may integrate patient characteristics, medication history, laboratory findings, pharmacogenomic information, and therapeutic response.⁴⁻⁷

The formulation domain is especially important because advanced dosage forms frequently contain interacting material and process variables. Conventional experimental development remains indispensable, but exhaustive empirical screening can be slow and resource intensive. Recent formulation literature describes increasing use of ML, surrogate modeling, Bayesian optimization, active learning, and automated experimentation to reduce

experimental burden and explore multidimensional design spaces.^{8–10}

At the clinical interface, AI is being investigated for prescription screening, adverse-event detection, medication management, pharmacometrics, adherence support, and personalized therapy. Recent pharmacy reviews suggest that implementation remains earlier and more workflow-oriented than in some other healthcare fields, making rigorous validation and outcome-focused studies a priority.^{11,12}

2. AI Technologies Relevant to Pharmaceutical Sciences

2.1 Machine learning and deep learning

Supervised ML methods—including regression, random forests, support vector machines, gradient boosting, and neural networks—can estimate pharmaceutical properties from labeled datasets. Unsupervised methods can identify clusters or latent structures, while semi-supervised approaches can exploit partially labeled datasets. DL extends these concepts through multilayer neural networks and is particularly useful for complex molecular, image, genomic, and textual data.^{5,6}

2.2 Natural language processing and generative AI

NLP can transform unstructured literature, patents, clinical notes, adverse-event reports, and regulatory documents into analyzable information. Generative AI and large language models (LLMs) add capabilities for information synthesis, document drafting, data extraction, and hypothesis generation. Their pharmaceutical use, however, requires verification because fluent output does not guarantee factual accuracy, reproducibility, or source fidelity.¹³

2.3 Reinforcement learning, Bayesian optimization, and active learning

Sequential optimization is highly relevant to formulation development. Bayesian optimization and active learning can select the next experiment based on previous observations and predicted uncertainty, reducing unnecessary experimentation. Reinforcement learning can also be used where decisions occur sequentially and actions affect future states. These methods are promising components of self-driving laboratory architectures.^{8–10}

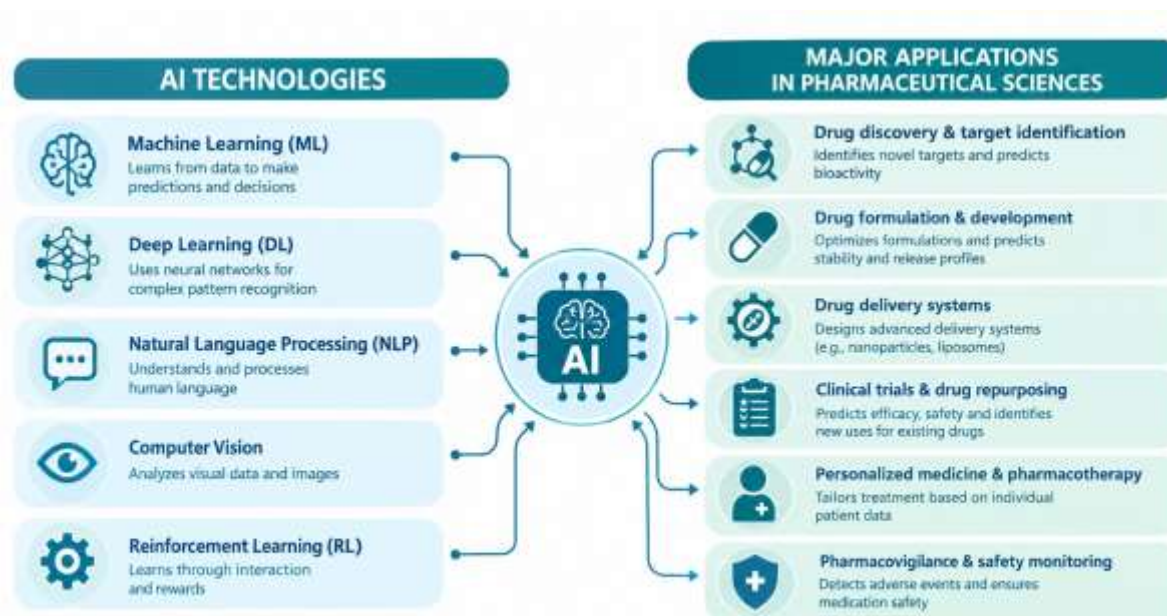


Figure 1. Artificial intelligence technologies and their major applications across pharmaceutical sciences.

Figure 1. Artificial intelligence technologies and their major applications across pharmaceutical sciences. Conceptual synthesis based on the pharmaceutical AI lifecycle described in references 5, 8, 14, and 15.

3. AI in Drug Discovery and Development

AI can support target identification, virtual screening, molecular-property prediction, lead optimization, toxicity assessment, pharmacokinetic prediction, and drug repurposing.^{5,6,14,15} Molecular representations can be processed with classical ML, graph-based approaches, or DL models to estimate biological activity and physicochemical behavior. Structural biology has also benefited from AI-based protein-structure prediction, exemplified by AlphaFold, although computational predictions still require experimental confirmation.⁶

In clinical development, AI can assist patient recruitment, trial-site selection, population stratification, endpoint analysis, protocol optimization, and identification of clinically relevant subgroups. A major limitation is that improved computational ranking does not automatically translate into successful clinical products; experimental validation, manufacturability, safety, and regulatory evidence remain decisive.^{14–16}

4. AI in Preformulation and Pharmaceutical Formulation

Preformulation generates information on solubility, pKa, lipophilicity, particle size, polymorphism, crystallinity, hygroscopicity, thermal behavior, and drug–excipient compatibility. AI can model relationships between molecular or material descriptors and these properties, allowing candidate materials and formulation strategies to be prioritized before extensive laboratory testing.^{8,9}

Formulation development can then be represented as a mapping from material attributes and process parameters to CQAs and performance outcomes. ML models may predict dissolution, disintegration, hardness, friability, particle size, encapsulation efficiency, drug loading, viscosity, release kinetics, and stability. Recent reviews describe AI as particularly useful when the response surface is nonlinear and several formulation objectives must be optimized simultaneously.^{8–10}

AI can complement Quality by Design (QbD) rather than replace it. QbD defines the scientific framework for identifying critical material attributes, critical process parameters, CQAs, and an acceptable design space. AI can provide a computational layer for estimating relationships within that design space, ranking experiments, and identifying regions requiring confirmation.^{9,17}

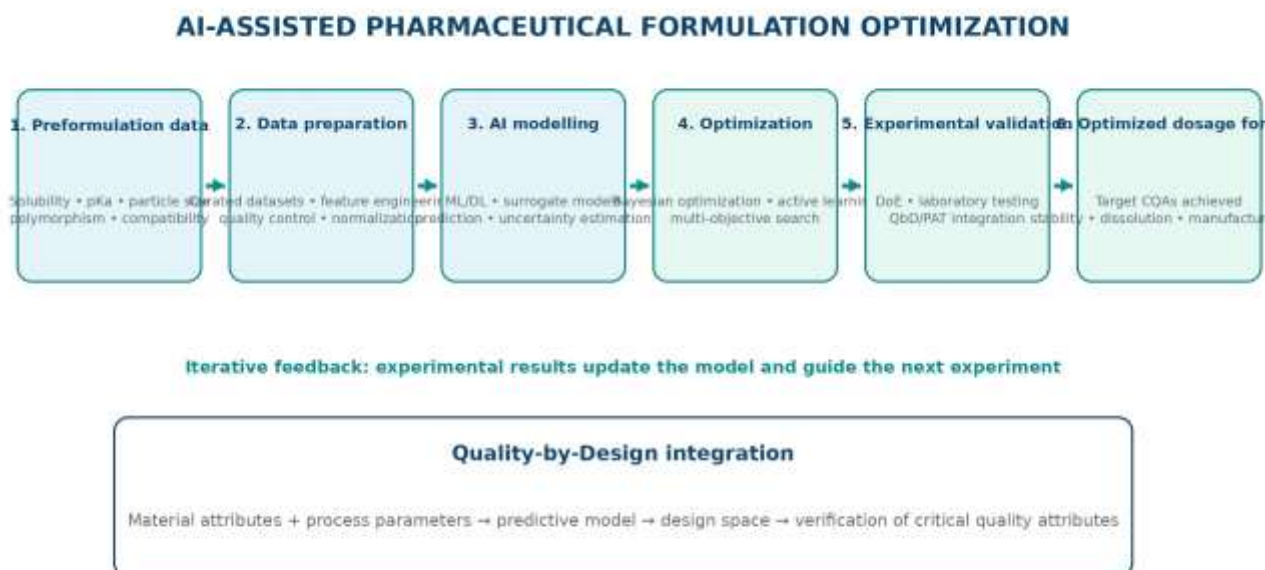


Figure 2. AI-assisted pharmaceutical formulation optimization workflow from preformulation data to optimized dosage-form development. The workflow reflects ML-guided formulation development, active learning, Bayesian optimization, and QbD concepts described in references 8–10 and 17.

5. AI in Advanced Drug-Delivery Systems

Advanced drug-delivery systems are characterized by complex interactions among formulation composition, particle engineering, manufacturing conditions, biological environment, and release behavior. AI has therefore attracted interest for nanoparticles, lipid nanoparticles, liposomes, polymeric carriers, nanocrystals, micelles, hydrogels, long-acting injectables, and stimuli-responsive systems.^{18–20}

For nanoparticulate systems, models can relate lipid or polymer composition and process conditions to particle size, polydispersity, encapsulation efficiency, drug loading, surface characteristics, stability, and release. A 2026 review of ML-enabled nanoparticulate formulation highlighted the growing role of predictive models in formulation design, optimization, and characterization while emphasizing the continuing need for experimental validation.¹⁸

AI-guided delivery development can be extended through surrogate modeling and multi-objective optimization. Instead of optimizing one response, researchers can seek formulations that simultaneously satisfy particle-size, loading, release, stability, and manufacturability constraints. This is particularly relevant to long-acting and controlled-release systems, where small changes in formulation or process conditions may alter release kinetics substantially.^{19, 20}

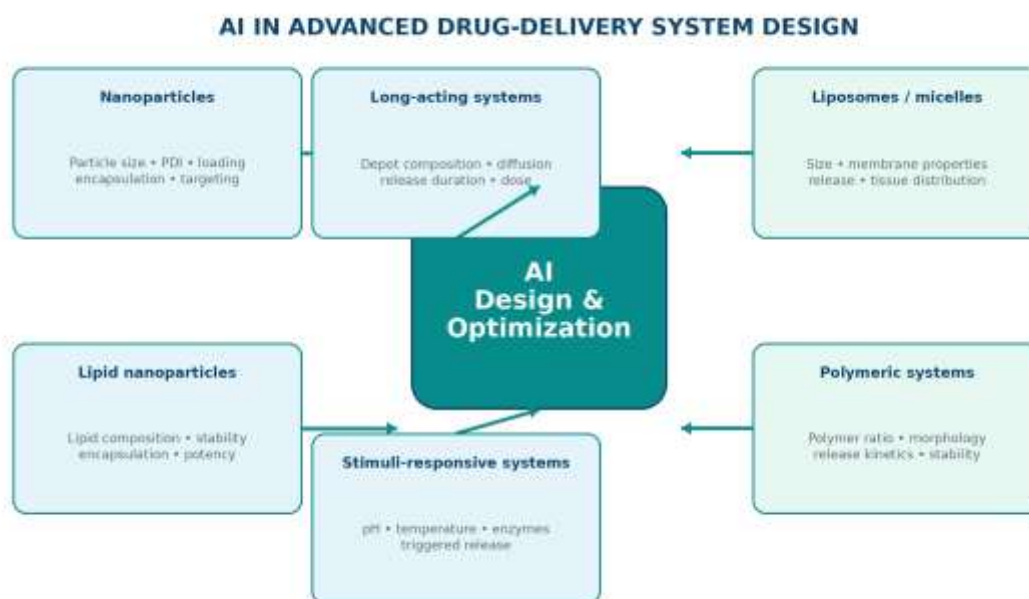


Figure 3. Application of artificial intelligence in the design and optimization of advanced drug-delivery systems. Conceptual framework informed by references 18–20.

6. AI in Pharmaceutical Manufacturing and Quality Control

AI is increasingly associated with Pharma 4.0 and data-driven manufacturing. Potential applications include predictive process modeling, process analytical technology (PAT), real-time quality monitoring, predictive maintenance, anomaly detection, process optimization, and supply-chain forecasting.^{17, 21}

For oral solid dosage forms, ML has been investigated for predicting granule properties, moisture content, extrusion behavior, and other process outcomes. The value of such systems is greatest when models are integrated with process knowledge and validated within the actual manufacturing context. Extrapolation between scales, equipment, sites, and raw-material lots remains a major challenge.²¹

Computer vision and spectroscopy can support automated inspection and analytical interpretation. Nevertheless, AI outputs used in GMP environments must remain traceable, auditable, and appropriately controlled. Model changes, data pipelines, software versions, and decision thresholds should be managed through a documented lifecycle consistent with the risk associated with the application.^{1–3, 21}

The completed quantitative dataset consisted of 200 SHG women. Participants were women aged 18–49 years who were members of selected SHGs, could understand Marathi or English, were willing to participate, and provided written informed consent. Women who had recently undergone structured reproductive health training, were unable to participate because of severe illness or disability, were absent during the intervention or post-test assessment, or withdrew consent were excluded. Purposive sampling was used to recruit eligible participants.

7. AI in Pharmacokinetics, Pharmacodynamics, and Clinical Trials

AI can complement conventional pharmacokinetic/pharmacodynamic (PK/PD) approaches by identifying nonlinear relationships between dose, exposure, patient characteristics, biomarkers, and response. Applications include clearance estimation, exposure prediction, therapeutic drug monitoring, dose optimization, and identification of patients at risk of subtherapeutic or toxic concentrations.^{12, 22}

Clinical development may benefit from AI-assisted patient identification, trial recruitment, site selection, population stratification, and analysis of heterogeneous endpoints. However, computational performance must be distinguished from clinical utility. Models should demonstrate appropriate calibration, discrimination, robustness, and prospective value within the intended population before influencing high-stakes decisions.^{14, 22}

8. AI in Personalized Pharmacy Practice

Personalized pharmacy seeks to move medication management from population averages toward decisions informed by individual characteristics. AI can integrate medication history, laboratory values, diagnoses, pharmacokinetic information, genomic data, adherence indicators, and patient-reported outcomes. Recent pharmacy reviews identify prescription screening, adverse-event detection, medication management, and patient-specific treatment prediction among the most developed applications.^{11,12}

Clinical pharmacists remain essential because treatment decisions involve contextual information, patient preferences, therapeutic goals, uncertainty, and ethical considerations that may not be captured by an algorithm. AI should therefore be positioned as a clinical decision-support layer rather than an autonomous prescriber.^{11,12}

9. AI, Pharmacogenomics, and Precision Pharmacotherapy

Pharmacogenomics provides information about genetic variation that may influence drug metabolism, transport, efficacy, and toxicity. AI can assist with interpretation of high-dimensional genomic and multi-omics data, identification of drug–gene relationships, patient stratification, and prediction of treatment response.^{23–25}

The strongest future models are likely to integrate pharmacogenomic information with pharmacokinetics, clinical characteristics, environmental exposures, and real-world outcomes. Such multimodal approaches may improve individualization, but they also intensify concerns about privacy, representativeness, genetic discrimination, and model transparency.^{23–25}

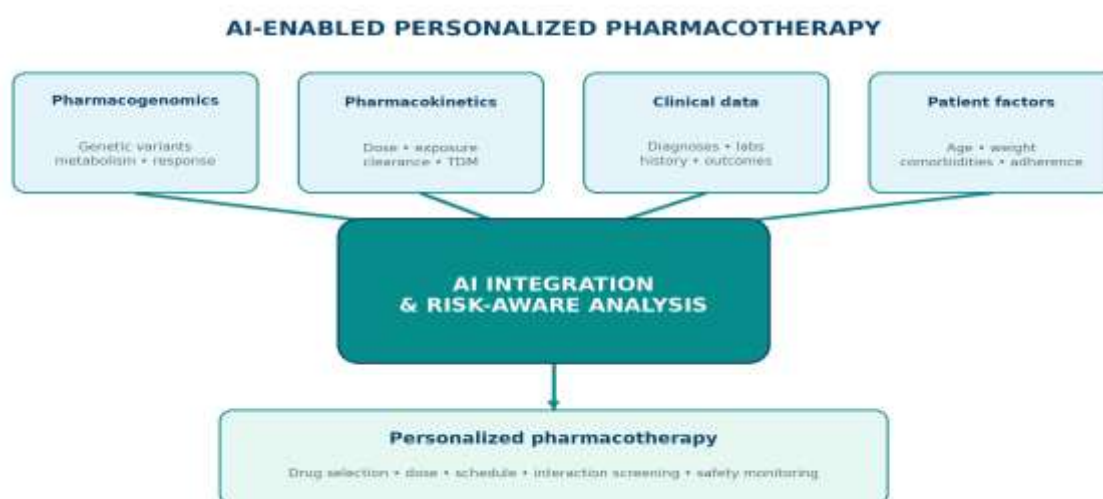


Figure 4. Integration of artificial intelligence, pharmacogenomics, pharmacokinetics, clinical data, and patient factors for personalized pharmacotherapy. Conceptual synthesis based on references 12 and 23–25.

10. AI in Personalized Formulation and 3D-Printed Medicines

Personalized formulation aims to tailor dose, dosage form, release behavior, route, or combination therapy to individual patient requirements. Three-dimensional (3D) printing is particularly relevant because it can produce dosage forms with adjustable geometry, porosity, drug loading, and release characteristics.^{26,27}

AI can support 3D printing by predicting printability, selecting process parameters, optimizing formulation composition, and modeling drug-release behavior. Recent reviews describe the convergence of AI, 3D printing, nanotechnology, and decentralized manufacturing as a potential route toward individualized medicines, including complex dosage forms and polypills.^{26–28}

This approach is particularly attractive for populations requiring flexible dosing, although implementation requires validated raw materials, reproducible printing, analytical verification, dose uniformity, stability assessment, and an appropriate regulatory framework. The concept should therefore be regarded as an emerging precision-pharmacy pathway rather than routine clinical practice.^{26–28}

11. AI in Pharmacovigilance and Medication Safety

Pharmacovigilance generates large quantities of structured and unstructured data. NLP, ML, and DL can support extraction of adverse drug events from clinical text, literature, safety reports, and other sources. A 2024 review

documented substantial interest in AI-assisted adverse-event extraction and signal-oriented analysis, while emphasizing variation in datasets and evaluation methods.²⁹ In pharmacy practice, AI may also support detection of prescription anomalies, interaction risks, duplicate therapy, and medication-related problems. These systems are most defensible when they prioritize cases for pharmacist review rather than making irreversible clinical decisions autonomously.^{11, 12, 29}

12. Generative AI and Large Language Models in Pharmacy

Generative AI can assist scientific information retrieval, literature synthesis, protocol drafting, patient education, documentation, and pharmaceutical knowledge management. In formulation science, emerging work proposes LLMs and generative models for hypothesis generation and interpretation of formulation information.¹³

However, generative systems can produce fabricated citations, incorrect interpretations, or confident but unsupported statements. For pharmaceutical research and patient care, outputs should be checked against primary sources and validated datasets. Sensitive patient information should not be entered into systems without appropriate privacy and governance controls. Current regulatory guidance reinforces the need for human-centric design, clear context of use, data governance, performance assessment, and lifecycle management.^{1–3}

13. Data Quality, Explainability, Bias, and Validation

AI performance is strongly dependent on data quality. Pharmaceutical datasets may be small, proprietary, heterogeneous, imbalanced, or generated under different laboratory conditions. Differences in analytical methods, equipment, excipient grades, patient populations, and data preprocessing can reduce generalizability.^{8, 18, 21}

Overfitting is another concern. High performance on a training dataset does not establish external validity. Appropriate development should include independent test data, external validation, uncertainty estimation, sensitivity analysis, and—where clinically relevant—prospective evaluation.^{2, 3}

Explainability is important when an AI output affects formulation selection, manufacturing decisions, or patient therapy. Yet explainability should be matched to risk and context rather than treated as a single universal requirement. Model cards, data documentation, feature-importance analysis, uncertainty reporting, and human review can improve transparency.^{1–3}

Algorithmic bias is particularly important in personalized pharmacy. Models trained on underrepresented populations may produce systematically poorer predictions for those groups. Inclusive datasets, subgroup analysis, fairness assessment, and continuous monitoring are therefore essential.^{23, 30}

14. Regulatory and Ethical Considerations

The FDA and EMA have moved toward risk-based, lifecycle-oriented approaches to AI. The EMA reflection paper considers AI across the medicinal-product lifecycle, from discovery through post-authorization activities.² The FDA's 2025 draft guidance proposes a credibility-assessment framework for AI models used to support regulatory decisions about safety, effectiveness, or quality.³ In January 2026, FDA and EMA also published ten guiding principles for good AI practice in drug development, emphasizing human-centric design, clear context of use, multidisciplinary expertise, data governance, risk-based performance assessment, and lifecycle management.¹

These principles have direct implications for pharmaceutical formulation. A model used to prioritize experiments has a different risk profile from a model used to release a commercial batch or recommend an individualized dose. The validation burden should therefore reflect the consequences of model error. AI should be embedded within established pharmaceutical quality systems rather than treated as an isolated software tool.^{1–3}

Ethically, AI implementation should preserve patient autonomy, confidentiality, equity, and professional accountability. In pharmacy practice, patients should not be denied meaningful human review merely because an algorithm has produced a recommendation. The pharmacist's role is likely to evolve toward interpretation, verification, communication, and shared decision-making.^{11, 12}

15. Future Perspectives

The next phase of pharmaceutical AI is likely to emphasize integration rather than isolated prediction. Self-driving laboratories could combine robotic experimentation, analytical testing, active learning, and automated decision-making to create closed-loop formulation development.^{8–10}

Digital twins may connect mechanistic process models with data-driven predictions for manufacturing and individualized therapy. In personalized medicine, AI may integrate pharmacogenomics, PK/PD, clinical data, and patient-generated information to support adaptive treatment strategies.^{23–25}

AI-assisted 3D printing could further connect patient assessment to on-demand manufacturing of individualized dosage forms.^{26–28} In manufacturing, real-time process models and PAT could support adaptive quality control, although uncertainty quantification, scale transfer, and regulatory validation remain important barriers.²¹ The future pharmaceutical ecosystem is therefore best represented as a connected lifecycle: discovery and target identification → formulation design → manufacturing and quality control → clinical pharmacy and personalized therapy → pharmacovigilance → feedback into development. Such a system can improve learning across the lifecycle while preserving human responsibility for high-stakes decisions.

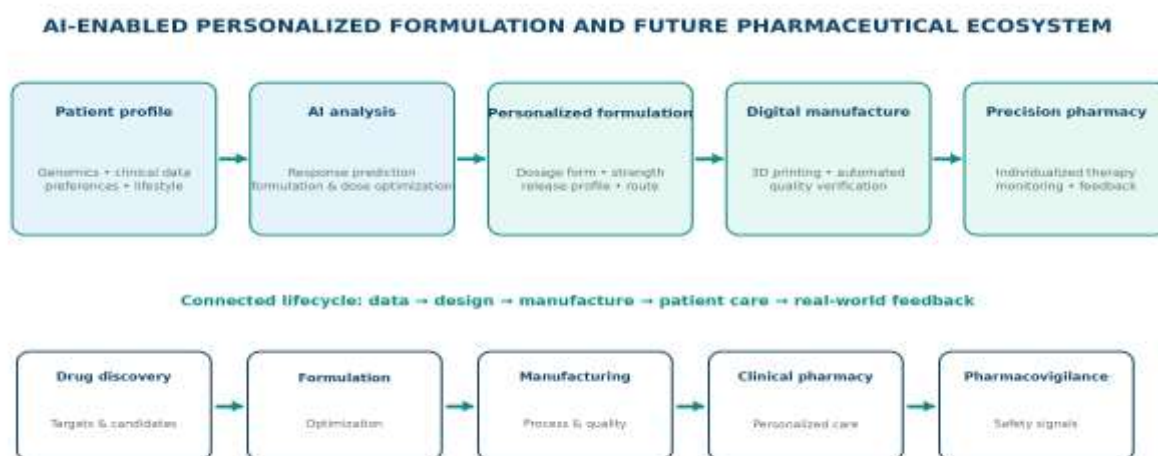


Figure 5. AI-enabled pathway for patient-specific pharmaceutical formulation and precision pharmacy integrated with the future pharmaceutical ecosystem. The figure combines the requested personalized-formulation and future-ecosystem concepts to comply with the journal's five-figure limit; informed by references 21 and 26–28.

16. Conclusion

AI is increasingly becoming a complementary technology across pharmaceutical formulation, drug development, advanced drug delivery, manufacturing, pharmacovigilance, and personalized pharmacy. ML and related optimization approaches can reduce experimental burden and support multidimensional formulation design, while AI-enabled delivery and 3D printing offer pathways toward individualized dosage forms. In clinical pharmacy, integration of AI with pharmacogenomics, pharmacokinetics, laboratory data, and medication histories may strengthen patient-specific decision support.

The principal barrier to translation is no longer simply algorithm availability. Reliable implementation requires high-quality data, external validation, uncertainty assessment, explainability appropriate to risk, protection against bias, cybersecurity, interoperability, and regulatory credibility. Current FDA and EMA frameworks reinforce a human-centric, context-specific, risk-based approach.^{1–3} The most credible future is therefore one in which AI augments—not replaces—pharmaceutical scientists and pharmacists, enabling a more predictive, adaptive, and patient-centered pharmaceutical ecosystem.

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