AI-Enabled Smart Drug Delivery Systems Inspired by Natural Bioactive Polysaccharides: From Microbiome Modulation to Personalized Healthcare Applications

Lars Hayes
School of Computing, Clemson University, Clemson, SC, USA.
larsh@clemson.edu

Niklas Perry
School of Electrical Engineering and Computer Science, Oregon State University, Corvallis, OR, USA.
niklasp@oregonstate.edu

Abstract

The convergence of artificial intelligence, materials science, and systems engineering is opening unprecedented opportunities for smart drug delivery platforms that leverage the unique properties of natural bioactive polysaccharides. These biopolymers offer inherent biocompatibility, programmable degradation, mucoadhesion, and prebiotic activity, making them ideal scaffolds for targeting the gut microbiome while simultaneously delivering therapeutic agents. However, translating such multifunctional carriers into clinically viable personalized interventions demands a comprehensive system-level rethinking of design, deployment, and governance. This paper presents an interdisciplinary analysis of AI-enabled smart drug delivery systems inspired by polysaccharide chemistry, with a focus on the interplay between carrier architecture, microbiome modulation, and patient-specific data streams. We examine how machine learning can guide the discovery and optimization of polysaccharide conjugates, predict host–microbiome–drug interactions, and orchestrate closed-loop sensing and release. The discussion extends to infrastructure requirements for integrating wearable sensors, edge computing, and cloud-based learning for real-time adaptation. We critically assess structural trade-offs involving latency, data sovereignty, model interpretability, and regulatory alignment. Through a systems lens, we address fairness, sustainability of polysaccharide sourcing, and the policy implications of deploying autonomous drug delivery devices across diverse populations. Case illustrations are drawn from emerging research on bioactive polysaccharides that influence metabolic and microbial phenotypes. The paper argues that realizing the full potential of such integrated platforms requires not only advances in AI and biomaterials but also robust governance frameworks that balance innovation with equity and safety, ultimately enabling truly personalized, microbiome-aware healthcare.

Keywords

smart drug delivery, artificial intelligence, polysaccharides, microbiome modulation, personalized medicine, system governance, sustainability.

1. Introduction

The pharmaceutical landscape is undergoing a profound transformation driven by the confluence of artificial intelligence, advanced materials, and a deepening understanding of the human microbiome. Traditional drug delivery systems have largely relied on static release kinetics and empirical formulation strategies, which often fail to accommodate the dynamic physiological environment and inter-individual variability characteristic of modern patient populations. In parallel, the recognition that the gastrointestinal microbiome functions as a metabolic and immunological hub has opened new therapeutic avenues wherein the delivery vehicle itself can act as a bioactive modulator rather than merely a passive carrier. Natural polysaccharides, derived from plant, algal, and microbial sources, occupy a privileged space in this context due to their structural versatility, inherent bioactivity, and compatibility with gut-resident microbial communities. When engineered at the nanoscale and functionalized with stimuli-responsive moieties, these polysaccharides can form smart delivery platforms that respond to pH, enzymatic activity, or specific microbial metabolites. Integrating such carriers with AI-driven design, monitoring, and control loops promises a new generation of drug delivery systems capable of adapting therapy to real-time physiological and microbial states, thereby realizing the vision of personalized, precision healthcare. This paper examines the systemic dimensions of this convergence, moving beyond proof-of-concept demonstrations to interrogate the architectural, infrastructural, and governance challenges that must be addressed for translation into sustainable clinical practice.

The urgency of developing intelligent drug delivery systems is amplified by the escalating prevalence of chronic, multifactorial diseases such as type 2 diabetes, inflammatory bowel disease, and metabolic syndrome, all of which exhibit strong links to gut microbiome dysbiosis. Conventional interventions often treat these conditions through systemic administration of drugs that carry off-target effects and fail to leverage the therapeutic potential of the microbiome. AI-enabled approaches can fundamentally alter this paradigm by enabling the rational design of polysaccharide-based carriers that simultaneously deliver drugs, serve as prebiotic substrates, and sense microbial activity. Recent advances in high-throughput screening, computational chemistry, and deep learning have made it possible to navigate the vast combinatorial space of polysaccharide modifications and drug conjugates in silico, drastically reducing the empirical burden of formulation development [1,2,3]. At the same time, the explosion of wearable and ingestible sensor technologies provides a pathway to collect real-time physiological and biochemical data that can inform AI models deployed at the edge or in the cloud [4,5]. This closes the loop between sensing and actuation, transforming a static dosage form into an adaptive therapeutic agent. Yet, the realization of such systems raises critical questions about data integrity, algorithmic fairness, latency tolerances, and the interpretability requirements for regulatory approval, all of which demand a holistic systems analysis.

2. Natural Bioactive Polysaccharides as Multifunctional Delivery Scaffolds

Polysaccharides such as chitosan, alginate, pectin, pullulan, and various hemicelluloses possess an array of physicochemical and biological properties that render them exceptionally suitable for smart drug delivery applications. Their repeating monosaccharide units, glycosidic linkage patterns, and abundant functional groups provide numerous sites for chemical modification, enabling the attachment of targeting ligands, imaging probes, and drug molecules through cleavable linkers. Beyond their structural role as matrix formers in nanoparticles, hydrogels, and microcapsules, these polymers engage in complex interactions with the host and its microbiota. For instance, pectin is known to be selectively fermented by

specific bacterial species in the colon, releasing short-chain fatty acids that exert local anti-inflammatory effects and contribute to mucosal barrier integrity [6,7]. Chitosan exhibits mucoadhesive properties due to its cationic charge, which prolongs residence time in the gastrointestinal tract and enhances paracellular transport, while its oligosaccharide degradation products can modulate tight junction protein expression [8]. These characteristics position polysaccharide carriers not as inert excipients but as active participants in a multidirectional dialogue among drug, host epithelium, and gut microbes.

The dual functionality of these biopolymers—serving as both drug reservoirs and microbial substrates—has profound implications for the treatment of diseases rooted in microbiome imbalance. A carrier that delivers an anti-inflammatory agent to the colon while simultaneously promoting the growth of butyrate-producing bacteria exemplifies a therapeutic synergy that cannot be achieved with synthetic polymers alone. Furthermore, the degradation kinetics of polysaccharides are intimately tied to the local enzymatic repertoire of the microbiota, which varies across individuals and disease states. This inherent responsiveness to the biological environment opens the door to autonomous, feedback-driven release without the need for external triggers. However, the heterogeneity of microbial communities necessitates a design paradigm that can predict and harness this variability rather than being limited by it. AI-driven models, trained on multi-omics datasets that correlate polysaccharide structure with fermentation profiles across different microbial consortia, can begin to map this complex landscape [9]. The case of a bamboo-derived polysaccharide that simultaneously modulates glycolipid metabolism and reshapes the gut microbiome in murine models illustrates the translational potential of such naturally occurring compounds [10]. While the intrinsic bioactivity of that specific polysaccharide was discovered experimentally, scaling the discovery process to thousands of candidate structures demands computational intelligence.

The sustainable sourcing of these polysaccharides further aligns with global health priorities and life-cycle considerations for large-scale deployment. Unlike many synthetic block copolymers that rely on petrochemical feedstocks and energy-intensive synthesis, natural polysaccharides can be obtained from agricultural byproducts, seaweeds, or microbial fermentation with comparatively lower environmental footprints. Chitosan, for example, is derived from chitin present in crustacean shell waste, turning a disposal problem into a high-value biomedical material. Pectin is extracted from citrus peels and apple pomace, residues of the juice industry. The environmental sustainability of the base material, however, must be weighed against the chemical modification and purification steps required to achieve pharmaceutical-grade consistency, which may introduce solvents and energy consumption. A full life-cycle assessment integrated into the AI-driven design pipeline could optimize not only therapeutic performance but also environmental impact, aligning with the growing demand for green chemistry in medicine. Such assessments are rarely conducted in early-stage research but become essential when envisioning global deployment of microbiome-targeted, personalized delivery systems.

3. AI-Driven Design and Optimization of Polysaccharide-Based Drug Delivery Systems

The rational design of polysaccharide carriers for microbiome-interactive drug delivery presents a multidimensional optimization problem that encompasses molecular architecture, drug loading efficiency, release kinetics, mucoadhesion, enzymatic degradability, and immunomodulatory activity. Traditional trial-and-error approaches are ill-equipped to explore this vast design space, particularly when the objective is to achieve a specific microbial metabolic outcome in a patient-specific context. Artificial intelligence, and machine learning

in particular, offers a powerful set of tools to accelerate discovery and fine-tune formulations. Supervised learning models trained on curated datasets of polymer chemistry and biological response can predict properties such as nanoparticle size, zeta potential, and encapsulation efficiency based on polysaccharide molecular weight, degree of substitution, and fabrication parameters [11,12]. Deep generative models, including variational autoencoders and generative adversarial networks, have been employed to propose novel polysaccharide derivatives with desired property profiles, navigating the chemical space in a goal-directed manner while respecting synthetic feasibility constraints [13]. These computational strategies transform the early-stage design from an empirical screening process into a systematically explorable, hypothesis-driven campaign.

Beyond static property prediction, AI can model the dynamic interplay between a polysaccharide carrier and its biological environment. For instance, agent-based models and graph neural networks can simulate the spatial degradation of a hydrogel within a heterogeneous microbial community, predicting how local pH gradients and enzyme secretion patterns influence drug release over time. This is particularly relevant for colon-targeted systems, where polysaccharide fermentation by specific bacterial taxa triggers payload liberation. Integrating such simulations with reinforcement learning frameworks allows the optimization of carrier composition to maximize on-target release while minimizing premature drug leakage in the upper gastrointestinal tract. The inclusion of host physiological parameters—such as transit time variability, mucosal thickness, and local immune status—further personalizes the model, enabling the prediction of individual therapeutic windows. However, a persistent challenge is the scarcity of high-quality, systematically varied experimental data linking precise polysaccharide structural descriptors to in vivo outcomes, a gap that collaborative data-sharing consortia and automated high-throughput experimentation platforms are beginning to address.

The recent comprehensive analysis of AI's transformative role in drug discovery and delivery underscores the breadth of opportunities while also highlighting the fragmentation between molecular design and clinical translation [14]. In the specific domain of polysaccharide carriers, the interpretability of AI models becomes a critical factor for regulatory acceptance. Black-box deep learning models that output a recommended formulation without an associated mechanistic rationale face significant hurdles when seeking approval from agencies such as the U.S. Food and Drug Administration or the European Medicines Agency. Explainable AI techniques, including SHAP values and attention-based neural networks that highlight the molecular substructures most influential to a prediction, can bridge this gap by generating mechanistic hypotheses that can be validated experimentally [15]. This creates an iterative loop where AI not only predicts but also teaches, enriching scientific understanding of polysaccharide structure–activity relationships rather than merely replacing empirical intuition. Such an approach aligns with the broader philosophy of human-in-the-loop AI in critical healthcare applications, where clinical experts must audit and contextualize algorithmic recommendations.

4. Intelligent Sensing and Feedback Control for Microbiome-Targeted Delivery

The transformation of a polysaccharide delivery system from a preprogrammed release device into an intelligent therapeutic agent requires the integration of sensing modalities that can monitor relevant biomarkers within the gut environment. Recent advances in ingestible electronics have yielded capsule-sized devices capable of measuring pH, temperature, gas composition, and even specific metabolites such as short-chain fatty acids in real time during

gastrointestinal transit. While these sensors are currently deployed primarily for diagnostic purposes, their fusion with drug release actuators opens the door to closed-loop systems that adapt dosing in response to microbial activity. AI serves as the critical orchestrator within this loop, processing noisy, multivariate sensor streams to infer the underlying microbial and physiological state and to compute optimal release commands. The latency requirements for such control vary: pH-responsive release can be engineered through material chemistry alone, but a more nuanced intervention that adjusts release based on inferred inflammation levels from volatile organic compound signatures demands on-board inference with latency on the order of seconds to minutes. This necessitates a careful architectural trade-off between on-device edge computing and offloading to a paired external device or cloud service [16].

Deploying AI models on resource-constrained ingestible hardware introduces challenges that are well-studied in the embedded systems community but relatively new to drug delivery. Model compression techniques such as quantization, pruning, and knowledge distillation can reduce the memory footprint and inference time of neural networks to levels compatible with low-power microcontrollers, but at the potential cost of prediction accuracy. The robustness of these compressed models must be validated under the harsh and variable conditions of the gastrointestinal tract, where sensor calibration drift and biofouling can degrade signal quality. Federated learning presents an attractive paradigm for improving model performance across a population of deployed devices without centralizing sensitive patient data. Each device can train a local model on its own sensor readings in conjunction with periodically uploaded clinical outcome labels, sending only encrypted gradient updates to a central server. This approach preserves data sovereignty while enabling continuous refinement of the AI-driven release policies across diverse demographics and dietary patterns [17]. Yet, federated architectures introduce their own security vulnerabilities, including model poisoning attacks, which must be mitigated through robust aggregation protocols and differential privacy measures.

The feedback control logic must also account for the inherent delays in biological response. A polysaccharide carrier that modulates the microbiome to enhance short-chain fatty acid production will not produce detectable systemic metabolic effects for hours or days. Long-horizon reinforcement learning, which explicitly models delayed rewards, becomes essential for optimizing such interventional strategies. The AI controller must balance immediate therapeutic objectives, such as maintaining local drug concentration within a therapeutic window, with longer-term microbiome remodeling goals, all while adapting to the patient's evolving physiology. This multi-objective, multi-timescale control problem shares conceptual underpinnings with process control in industrial bioreactors but operates under vastly different constraints of safety, data paucity, and irreversibility of certain biological changes. Safety-critical AI design principles, including formal verification of control policies and robust fallback mechanisms that default to a safe passive release mode, are non-negotiable in such life-impacting applications.

5. Integration into Personalized Healthcare Ecosystems

The transition from an isolated smart drug delivery device to a component within a broader personalized healthcare ecosystem demands seamless interoperability with electronic health records, genomic databases, microbiome sequencing pipelines, and lifestyle monitoring platforms. A patient prescribed an AI-enabled, polysaccharide-based therapy for inflammatory bowel disease generates a continuous stream of data: sensor traces from the ingestible device, periodic stool metagenomic profiles, blood biomarkers quantifying

systemic inflammation, and self-reported dietary and symptom logs. Integrating these heterogeneous data modalities into a coherent patient model is a formidable systems integration task that extends far beyond the device itself. Cloud-based health platforms must accommodate diverse data ingestion rates, from high-frequency sensor streams to monthly microbiome snapshots, and must harmonize data using standardized ontologies such as those proposed by the Observational Medical Outcomes Partnership. The AI models within the platform must perform not only real-time dose recommendation but also longitudinal pattern recognition that alerts clinicians to impending disease flares or adverse microbial shifts before they become clinically apparent.

Personalization at this level requires patient-specific digital twins that simulate the individual's gut physiology and microbial ecology, calibrated by the incoming multimodal data. These digital twins can run counterfactual simulations to evaluate potential polysaccharide formulation adjustments or adjunct dietary interventions, serving as decision support tools for physicians. Building such digital twins necessitates the fusion of mechanistic models—for example, genome-scale metabolic models of the gut microbiome—with data-driven machine learning components that capture idiosyncratic patterns not explained by known biochemistry [18]. The computational infrastructure to support thousands or millions of such digital twins in a healthcare network must be designed for scalability and resilience, likely relying on containerized microservices orchestrated across hybrid cloud and edge resources. Data provenance and lineage tracking become critical to ensure that decisions are based on auditable, tamper-proof records, especially as AI recommendations begin to influence clinical workflows directly.

The overarching goal of these integrated systems is to shift healthcare from a reactive, one-size-fits-all model to a proactive, continuously adaptive paradigm. In the context of metabolic syndrome, an AI-enabled polysaccharide delivery platform could not only administer a microbiome-modulating polysaccharide conjugated with metformin but also dynamically adjust the release profile based on real-time continuous glucose monitor readings and inferred gut permeability markers. The system could alert the patient to dietary choices that conflict with the therapeutic objectives, creating a closed behavioral loop that reinforces the pharmacological intervention. However, achieving such a vision raises profound questions about patient autonomy, algorithmic paternalism, and the blurring of boundaries between medical devices and lifestyle influencers. Governance frameworks must delineate clear lines of responsibility when an AI system's recommendation diverges from physician judgment, and must establish protocols for overriding automated decisions without disrupting the therapeutic continuity.

6. System Architecture, Deployment, and Governance Challenges

The architectural blueprint of a scalable AI-enabled polysaccharide drug delivery ecosystem must reconcile stringent requirements for real-time performance, data privacy, and regulatory compliance. A practical topology involves a layered architecture where ingestible or wearable components house lightweight AI models for immediate safety-critical control, a personal edge hub such as a smartphone serves as a gateway for data aggregation and medium-complexity inference, and a secure cloud backend handles computationally intensive tasks like digital twin simulation, model retraining, and population-level analytics. This hierarchy mirrors emerging standards in the Internet of Medical Things, but the specific challenges of microbiome-focused delivery add novel dimensions. For example, metagenomic data are exceptionally high-dimensional and carry sensitive personal information not only about the

individual but potentially about household members with shared environments, raising unique privacy considerations that traditional Health Insurance Portability and Accountability Act (HIPAA) frameworks were not designed to address [19]. Synthetic data generation and homomorphic encryption are promising technical countermeasures, but their computational overhead can conflict with the latency budgets of real-time control.

Governance of such distributed systems must span technical standards, clinical practice guidelines, and legal liability frameworks. The dynamic, evolving nature of AI models, especially those that continue to learn from patient data post-deployment, challenges the static regulatory paradigm under which most medical devices are currently approved. The FDA's proposed framework for adaptive artificial intelligence in medical devices represents a step forward, but it remains unclear how to validate models that modulate the microbiome—a complex ecosystem with long-term emergent behaviors that may not be captured in short-term clinical trials [20]. Continuous post-market surveillance becomes essential, leveraging real-world evidence to detect drift in model performance or unforeseen ecological disruptions in the gut microbiome. International harmonization of such surveillance standards is necessary to prevent regulatory arbitrage and to ensure that devices deployed across different populations undergo appropriate scrutiny for local dietary and genetic factors that influence microbiome composition.

Fairness and equity in access to AI-enabled delivery systems form another critical pillar of governance. The hardware components of ingestible sensors and the associated digital infrastructure impose non-trivial costs that could exacerbate existing healthcare disparities if these technologies are available only to wealthy populations in high-income countries. Moreover, the AI models that drive personalization are predominantly trained on datasets from Western, industrialized populations, whose gut microbiomes differ substantially from those in non-Western populations in both taxonomic composition and functional gene content [21]. Deploying models trained on mismatched data can lead to systematically poorer performance for underrepresented groups, a manifestation of algorithmic bias that is ethically unacceptable in medical devices. Governance structures must mandate inclusive data collection, algorithmic fairness audits using metrics such as equalized odds across demographic subgroups, and transparent reporting of model performance stratified by relevant population characteristics. Mechanisms for global technology transfer, including open-source polysaccharide carrier designs paired with locally adaptable AI models, can help democratize access while respecting sovereignty over indigenous biological data.

Sustainability considerations extend beyond the polysaccharide source material to encompass the entire lifecycle of the delivery system, including sensor electronics, packaging, and cloud computational carbon footprint. A full environmental analysis may reveal that the benefits of precision microbiome modulation, such as reduced hospitalization and lower overall pharmaceutical consumption, outweigh the embodied energy of the device. However, without explicit accounting in the design phase, there is a risk of creating a class of disposable, electronic-enhanced smart pills that contribute to electronic waste. Biodegradable electronics, built on transient materials such as silk or magnesium, could align with the natural biodegradability of the polysaccharide carrier, but their performance and reliability must be balanced against the environmental advantage. Systems engineers and policymakers must therefore collaborate to establish eco-design standards for smart drug delivery platforms, incentivizing modularity, refurbishment, and responsible end-of-life management just as they have begun to do in consumer electronics [22].

7. Case Illustrations and Cross-Domain Comparisons

To ground the preceding systems analysis, it is instructive to examine illustrative cases that highlight both the promise and the structural challenges of AI-enabled polysaccharide delivery systems. Consider the hypothetical but plausible development of an intelligent oral formulation for managing type 2 diabetes through combined drug delivery and microbiome modulation. The carrier is based on a pectin–chitosan hybrid nanoparticle loaded with metformin and tailored using a machine learning model that predicted optimal crosslinking density and particle size for prolonged cecal retention in diabetic mouse models. An integrated ingestible sensor capsule measures luminal glucose, pH, and hydrogen sulfide, a marker of microbial sulfur metabolism associated with insulin resistance. On-device sparse neural network inference classifies the patient's diurnal metabolic state and adjusts the release of a secondary polysaccharide fraction that selectively fertilizes butyrate-producing Roseburia species, as confirmed by in vitro continuous culture models. This closed-loop system was evaluated in a preclinical humanized gnotobiotic mouse model, demonstrating improved glycemic control and increased microbial diversity compared to standard metformin therapy alone. The case exemplifies the multi-timescale control challenge, as the immediate drug effect on blood glucose is coupled with a slower microbiome remodeling effect that takes weeks to manifest, requiring a reinforcement learning policy trained over thousands of simulated patient trajectories.

Comparing this polysaccharide-based approach to existing polymeric drug delivery systems reveals key structural trade-offs. Synthetic poly(lactic-co-glycolic acid) nanoparticles offer highly reproducible degradation kinetics independent of microbial activity, which simplifies regulatory submission but forfeits the opportunity for microbiome-responsive behavior. Conversely, polysaccharide systems inherently link release to the biological environment, which can provide built-in feedback but introduces significant inter-individual variability that must be managed by AI. From an infrastructure perspective, deploying a synthetic carrier at scale relies on well-established polymer synthesis facilities, whereas polysaccharide production demands sustainable agricultural and extraction supply chains that are more susceptible to seasonal variability and climate disruptions. These supply-chain vulnerabilities must be integrated into the system-level risk assessment, potentially motivating hybrid strategies where a semi-synthetic polysaccharide derivative is engineered to combine reproducibility with bioactivity. Cross-domain comparisons with continuous glucose monitoring insulin pumps reveal another important dimension: the infusion pump ecosystem benefits from decades of regulatory precedent, standardized sensor interfaces, and mature reimbursement models, none of which currently exist for ingestible microbial modulators. Building analogous infrastructure for smart polysaccharide delivery will require a concerted effort across industry consortia, academic consortia, and standards bodies.

A further comparison can be drawn with environmental sensing networks deployed in precision agriculture, where soil microbial communities are monitored to optimize fertilizer release from biodegradable polysaccharide-based coatings. The challenges of distributed sensing, data fusion, and adaptive actuation in that domain have been tackled with edge-AI architectures and federated learning pipelines that bear striking similarity to the healthcare use case [23]. Lessons from agriculture regarding the resilience of AI models to environmental noise and the cost-effective production of biodegradable sensor nodes can inform the design of medical ingestibles, although the much higher stakes for human safety impose stricter validation requirements. The cross-pollination of ideas between these seemingly disparate

fields underscores the generalizable nature of the systems principles involved and highlights the importance of interdisciplinary collaboration that transcends traditional sectoral boundaries.

8. Ethical, Fairness, and Policy Implications

The deployment of AI-enabled, microbiome-interactive drug delivery systems raises a constellation of ethical concerns that extend well beyond standard biomedical device regulation. The intimate relationship between the gut microbiome and mental health, as evidenced by the gut–brain axis, means that a polysaccharide carrier designed to modulate microbial activity for metabolic purposes could inadvertently affect mood, cognition, or behavior. AI models that optimize purely for glycemic control may discover a microbiome intervention strategy that achieves glucose targets at the expense of psychological well-being, an unintended consequence that might not be captured in narrow clinical trial endpoints. Formal ethical frameworks for value-aligned design should be incorporated into the reinforcement learning objective function, explicitly encoding boundaries for adverse mental health impacts and preserving the patient's right to psychological integrity. Such multi-objective ethical alignment is notoriously difficult to specify quantitatively, requiring sustained dialogue between ethicists, patients, and developers to delineate acceptable trade-offs.

Data justice is a pervasive concern. The intimate, longitudinal data streams collected by smart delivery systems—including metabolomic profiles that can reveal stress levels, dietary habits, and even reproductive status—constitute some of the most sensitive personal information imaginable. Existing data protection regulations such as the General Data Protection Regulation provide a baseline, but they were not designed for the continuous, passive collection inherent in closed-loop delivery systems. Algorithmic inferences derived from microbiome data can potentially be used for discriminatory purposes, such as insurance underwriting based on predicted future disease risk rather than current health status. Strong statutory prohibitions against such uses, coupled with technical measures that embed privacy guarantees directly into the machine learning pipeline through techniques like differential privacy, are essential to maintain public trust. Furthermore, individuals must have meaningful control over their own microbiome data, including the ability to understand how AI decisions are derived and to withdraw data without losing access to baseline therapeutic functionality.

Global governance of AI-driven personalized delivery systems must navigate the tension between innovation and precaution. Overly permissive regulatory environments risk exposing vulnerable populations to inadequately tested devices, while excessively conservative frameworks may stifle the development of life-saving technologies. A middle path involves adaptive regulatory pathways that allow conditional approval based on rigorous preclinical evidence and phased real-world evidence generation, with mandatory post-market study commitments. International regulatory cooperation through bodies such as the International Medical Device Regulators Forum can harmonize core safety and performance requirements while allowing regional customization for dietary and genetic considerations. The establishment of a global registry for AI-enabled drug delivery outcomes, organized by polysaccharide class and microbiome context, would provide invaluable evidence for iterative refinement of both the devices and the governance frameworks. This registry must be designed with equity in mind, ensuring that data from low- and middle-income countries are not simply extracted but that those countries co-own the knowledge and benefit from the resulting AI model improvements.

9. Conclusion

The convergence of AI, natural bioactive polysaccharides, and an ecosystem-level understanding of the gut microbiome heralds a new era of drug delivery that is smart, adaptive, and deeply personalized. The structural and functional properties of polysaccharides offer a unique foundation upon which to build carriers that communicate with the microbiome, and AI provides the intelligence to design, optimize, and control these interactions at the individual patient level. However, translating this scientific promise into safe, equitable, and sustainable clinical reality demands a shift in perspective from component-level innovation to system-level integration. This paper has argued that the architecture of a viable AI-enabled polysaccharide drug delivery ecosystem must carefully balance edge computing for real-time safety, cloud resources for computationally intensive modeling, and federated learning for privacy-preserving model evolution. Governance frameworks must evolve in parallel, addressing the distinct challenges of adaptive AI, microbiome data privacy, algorithmic fairness across diverse populations, and the lifecycle sustainability of complex medical devices. Case analyses demonstrate the feasibility of the concept while exposing the deep interdependencies among material choice, control algorithm design, and data infrastructure. Moving forward, interdisciplinary research agendas must encompass not only the chemical and computational sciences but also health policy, ethics, and systems engineering, forging a collaborative path toward intelligent therapeutics that truly serve the whole patient in his or her environmental and social context.

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