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AI-Driven Drug Development and Regulatory Submission: A Global Perspective

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Abstract: Artificial intelligence (AI) has become an important driver in the pharmaceutical value chain and is transforming the way new medicines were discovered, developed, tested and regulated. Machine learning, deep learning, natural language processing, graph neural networks and generative AI are now embedded in target identification and virtual screening, lead optimization, pre-clinical toxicity prediction, clinical trial design and post-market pharmacovigilance. Simultaneously, regulatory authorities worldwide such as the United States Food and Drug Administration (FDA), the European Medicines Agency (EMA), Japan's Pharmaceuticals and Medical Devices Agency (PMDA), and the International Council for Harmonization (ICH)- have started to develop the frameworks that govern the credibility, transparency, and lifecycle management of artificial intelligence (AI) systems applied to generate regulatory evidence. This review synthesizes current literature to provide an integrated global view of AI-driven drug development and regulatory submission. We describe the technological foundations of pharmaceutical AI, follow its application along the discovery-to-post-market continuum, critique the FDA's risk-based credibility assessment framework from January 2025, and compare it with the broader lifecycle approaches of the EMA, NMPA, and PMDA. We also discuss ongoing challenges data quality and bias, model interpretability, regulatory harmonization, workforce readiness, and the lack of universal standards and propose priority actions for regulators, sponsors, and academia. Realizing the full capabilities of AI in pharmaceutical development and regulation will necessitate concerted, interdisciplinary efforts that balance innovation with patient safety, transparency, and equity.

Keywords: *Artificial Intelligence; Machine Learning; Deep Learning; Drug Discovery; Drug Development; Regulatory Science; FDA; EMA; NMPA; PMDA; Pharmacovigilance; Global Harmonization.*

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I. INTRODUCTION

The discovery, development and regulatory approval of a new medicine is one of the most expensive and time-consuming undertakings in modern science. Current estimates suggest the cost to develop a single new drug is over two billion US dollars and development times are often in excess of ten years and approximately ninety percent of candidates entering clinical trials fail to gain approval [1,6,7,23]. These persistent inefficiencies, termed in the literature as the slow decline in pharmaceutical research and development productivity, have provided strong incentives for the adoption of computational approaches that can accelerate target identification, compound screening, and clinical evaluation and reduce attrition [6].

Artificial intelligence (AI), machine learning (ML), deep learning (DL), natural language processing (NLP), graph neural networks (GNN), and generative AI (Gen-AI)) has gone from a niche research tool to a core foundation of pharmaceutical innovation over the last decade [1,3,11]. Major pharmaceutical companies now embedded AI throughout their research and development pipelines, and regulatory agencies have started to receive a growing number of drug applications with AI/ML components: the FDA alone saw an increase from 29 such submissions in 2019 to over 500 cumulative submissions by 2023 [4,17].With this rise in adoption has come a growing awareness among regulators that artificial intelligence systems used to create or form the basis of regulatory evidence need to be spoke oversight frameworks.

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The FDA's January 2025 draft guidance, "Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products," is the first agency-widely effort to define a risk-based credibility assessment process for such systems [4,8]. More extensive activities with some similarities have been started by the European Medicines Agency (EMA), China's National Medical Products Administration (NMPA) and Japan's Pharmaceuticals and Medical Devices Agency (PMDA) [2,5,14,15,16].

This review summarizes the current literature on AI-enabled drug development and the intersection of global regulatory science. Section 2 outlines the core AI tools applied across the pharmaceutical value chain. Sections 3 through 5 trace AI applications from discovery to preclinical and clinical development. Section 6 describes regulatory structures for AI in drug and biological product review, focusing on the FDA's seven-step credibility framework. Section 7 addresses the comparative global analysis of regulatory divergence and harmonization efforts. Section 8 discusses AI in post-market pharmacovigilance. Section 9 describes cross-cutting challenges. Section 10 describes future directions.

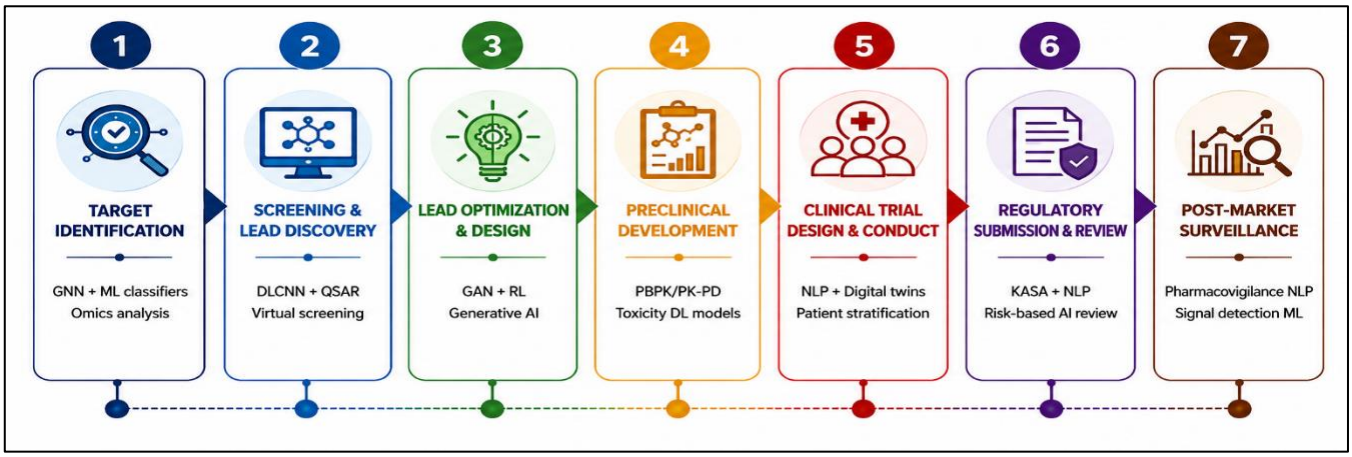

Fig 1 Provides an Overview of the Way the AI Technique Families Described in Section 2 Map onto the Seven Major Stages of the Drug Development and Regulatory Continuum, from Target Identification to Post-Market Surveillance; the Rest of this Section Focuses on the Discovery-Stage Applications.

II. ARTIFICIAL INTELLIGENCE TECHNOLOGIES IN THE PHARMACEUTICAL VALUE CHAIN

AI is best understood of nested family of computational approaches, not a single technology. Machine learning (ML) refers to a subset of AI that includes algorithms like support vector machines, random forests, and gradient boosting that allow systems to improve their performance on a task by being exposed to data, rather than being explicitly programmed [1,3]. Deep learning is a subfield of ML that uses multi-layer artificial neural networks such as convolutional neural networks (CNNs) for image- and structure-like data, recurrent neural networks (RNNs) for sequential data including protein or chemical sequences, and transformer architectures that form the basis of modern large language models [1,5]. Natural language processing uses these architectures to analyze unstructured text such as scientific literature, patents, clinical narratives and regulatory documents while graph neural networks operate on molecular graphs and biological networks to capture non-Euclidean structural relationships [1]. Generative AI (e.g. generative adversarial networks (GANs) and diffusion models) is increasingly used for de novo molecule and protein design [1,3]. Figure 2 summarizes the hierarchy of these technique families in application to pharmaceutical research. Protein language models such as ESM-2 and structure-prediction systems such as AlphaFold are examples of the merging of transformer models from NLP with structural biology, treating amino-acid sequences as a biological "language" to predict three-dimensional protein folds with near-experimental accuracy [1,9]. This convergence is directly relevant for drug discovery as accurate structural models materially increase the fidelity of virtual screening and structure-based drug design.

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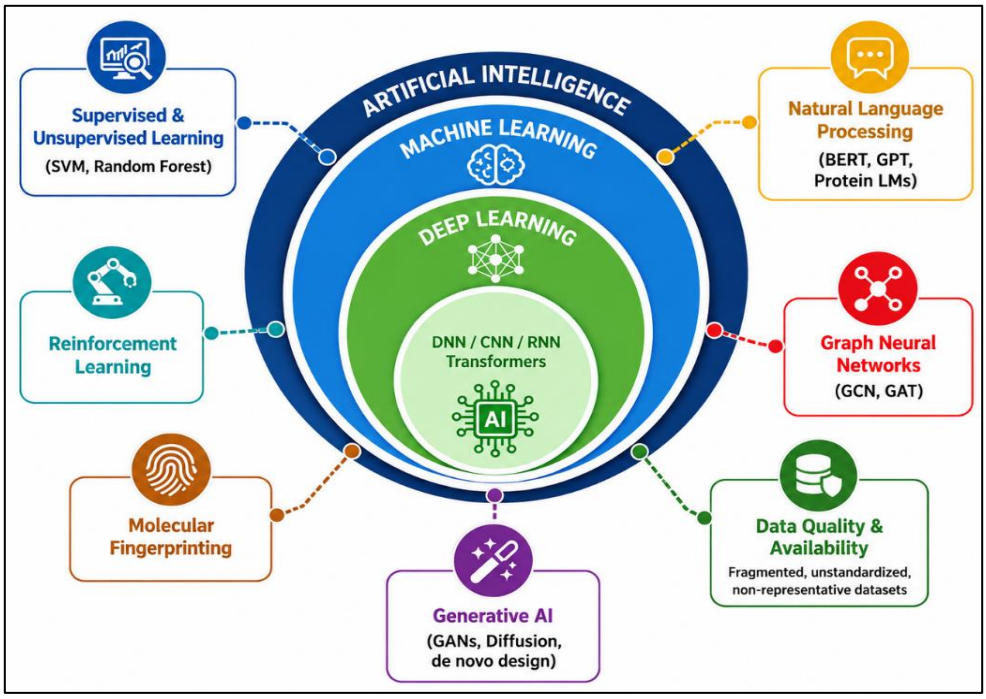

Fig 2 Taxonomy of Artificial-Intelligence Techniques Applied Across the Pharmaceutical Value Chain, Showing the Nested Relationship Between AI, Machine Learning, and Deep Learning, Together with Adjacent Technique Families (NLP, GNNs, Generative AI, Reinforcement Learning, and Molecular Fingerprinting).

III. DISCOVERY OF DRUGS USING AI

A. Identification and Validation of Targets

AI improves target identification by fusing multiple types of genomic, proteomic, and clinical data, including DrugBank and PubChem, to discover disease-associated genes and evaluate protein drug ability in a more comprehensive way than the conventional single-modality approach [1]. Supervised learning models trained on gene-expression and disease-status datasets can predict disease risk and implicate candidate genes whereas unsupervised clustering techniques reveal novel disease subtypes from high-dimensional omics data [1].

B. Virtual Screening and Identification of Leads

ML-powered quantitative structure–activity relationship (QSAR) models enable in silico screening of extensive chemical libraries, allowing prioritisation of compounds with a high probability of target engagement, and significantly reducing reliance on resource-demanding high-throughput screening [1,25]. Platforms like Atomwise use deep learning to screen large compound libraries against protein targets, whilst data-integration platforms like BenevolentAI leverage scientific literature, clinical trial data and genetic information for aiding in novel target and compound identification [1].

C. Lead Optimization and De Novo Molecular Design

Generative architectures, such as GANs, variational autoencoders and reinforcement learning agents, explore chemical space beyond available compound libraries while optimizing molecular properties, such as bioactivity, solubility and toxicity [1,3]. Diffusion-based generative modeling has been applied to protein–ligand docking (e.g. tools such as DiffDock), and the development of a fully AI-generated small-molecule candidate for idiopathic pulmonary fibrosis by Insilico Medicine which began Phase IIa clinical trials in March 2024 exemplifies the transition of generative AI from a research tool to a source of clinical candidates [1,4].

D. Drug Repurposing

AI-driven drug repurposing frameworks, including DeepPurpose and MultiDCP, utilize deep learning to predict drug-target and drug-disease associations from heterogeneous molecular and clinical data, facilitating systematic identification of new indications for existing, already-characterised compounds [1,12]. The repurposing of baricitinib (a drug first approved for rheumatoid arthritis) as a COVID-19 therapy, enabled by AI-driven literature and network analysis, shows the practical value of such an approach, but repurposed drugs still have weaker method-of-use patent protection and hence lower commercial incentives [1].

IV. AI FOR PRECLINICAL DEVELOPMENT

In the pre-clinical setting, artificial intelligence can predict ADMET properties, drug-drug interactions and toxicity endpoints based only on chemical structure, allowing safer candidates to be prioritised before they are ever exposed to animals or humans [1,2]. Regulators increasingly favour market-pull rather than technology-push innovations, with comparatively lower risk of regulatory rejection, such as physiologically based pharmacokinetic (PBPK) modelling platforms like SimCYP, GastroPlus and PK-Sim, which combine mechanistic pharmacology with AI-assisted parameter estimation [2].

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In 2025 the FDA announced the removal of mandatory animal testing requirements for certain classes of products in favor of AI-based models and other New Approach Methodologies (NAMs) such as organ-on-a-chip systems and in silico simulation, marking a significant change in the regulatory landscape toward computational preclinical evidence [4]. However, reviewers caution that the preference for in silico models over in vivo models may make late-stage product failures more likely in the absence of adequate verification of AI-generated predictions with additional clinical evidence. This implies that, for now, AI should be used to complement rather than supplant conventional methods.

V. AI FOR CLINICAL TRIAL DESIGN AND EXECUTION

AI is applied during clinical development to optimise trial design, facilitate patient recruitment, monitor safety in real time and manage adaptive protocols. Machine learning algorithms using historic trial data can guide optimal sample size, endpoint selection and suitable patient subpopulations, and NLP-based eligibility-matching tools reduce the burden of manual patient screening [1,2].

A. Virtual and Decentralised Clinical Trials

AI-powered "digital twin" methods model disease progression and predict individual treatment response by simulating virtual patient populations, allowing for decentralised trial designs that reduce the need for large control groups and minimise trial participation burdens for patients and investigator sites [1,2]. Internet-of-Things devices automated glucometers, wearable sensors, blood-pressure cuffs stream physiological data that feeds these models in near real-time.

B. Predictive Analytics on Trial Success

Random-forest and NLP-based models have demonstrated the ability to predict transitions between clinical trial phases with high accuracy by assessing unstructured eligibility-criteria text and identifying variables that are most predictive of Phase 2 and Phase 3 outcomes [2]. Bayesian adaptive trial designs such as the I-SPY 2 breast-cancer platform trial demonstrate how probabilistic AI-assisted frameworks can enable the continuous evaluation of multiple treatment arms and the more efficient dropping of ineffective therapies than fixed, discrete trial designs an approach that regulators increasingly see as translatable to the validation of AI models themselves [4].

C. Case Study: The Limitations of AI-Enabled Clinical Decision Support

Not all AI clinical applications have been a success. A prime example is IBM Watson for Oncology, which was trained predominantly on treatment protocols from a single cancer center in the United States, and when deployed internationally, made recommendations that did not align with local standards of care. Physicians in South Korea agreed with its recommendations only 49% of the time, and oncologists in Denmark ceased using the tool after finding recommendations ill-suited to their health-system constraints [4]. This example emphasises the importance of external validation, the representativeness of local data, and structured monitoring of the lifecycle before deploying AI clinical-decision tools in new populations or health systems [4].

VI. AI IN REGULATORY SUBMISSION & REVIEW

As AI models move from exploratory research tools to systems that directly generate evidence in support of regulatory submissions, agencies around the world have started to define structured oversight mechanisms. This section provides a summary of the main frameworks issued by the FDA, EMA, NMPA, PMDA and ICH.

A.FDA's Risk-Based Credibility Assessment Framework

In January 2025, the FDA issued its first dedicated guidance on AI for regulatory decision-making for drug and biological products, developed collaboratively across the Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), and several other agency divisions [4,8]. Guidance broadly defines AI as a machine-based system that can make predictions, suggestions, or judgments that impact real or virtual environments based on human-defined objectives and establishes a seven-step, risk-based credibility assessment process intended to align the rigor of validation with the potential consequences of model error [4].

Figure 3. The FDA's seven-step risk-based credibility assessment framework for AI models supporting regulatory decision-making (adapted from FDA draft guidance, January 2025).

Within this framework, AI applications directly used to generate evidence for regulatory submissions – e.g., patient stratification algorithms, dose-optimization tools, or safety-

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signal detection systems – are subject to the highest level of scrutiny, whereas systems supporting internal decision-making or operational efficiency are subject to proportionally eased requirements [4]. Models are categorized as high, medium or low risk according to the severity and likelihood of harm from an incorrect prediction; high-risk applications such as those determining eligibility for life-saving therapies for trials or defining primary endpoints in pivotal trials require comprehensive validation including multiple independent datasets, formal bias assessments across demographic subgroups and demonstrated explainability [4].

One of the main constraints of current guidance is the explicit exclusion of artificial intelligence systems used solely for drug discovery or internal operational improvement, although discovery-phase tools (e.g., an AI platform used to identify a target which subsequently informs clinical trial design) can indirectly influence downstream regulatory evidence [4]. This scope boundary adds a layer of interpretive uncertainty for sponsors developing integrated AI platforms across multiple development phases.

The guidance also talks about lifecycle management, and that AI models are vulnerable to concept drift (the relationship between inputs and outputs may change over time) and data drift (the distribution of the input data may change due to changing patient demographics or clinical practices) [4]. As an illustrative example, Google Health's diabetic-retinopathy screening system achieved 90% sensitivity and 98% specificity on validation datasets from the United States and India, but only 73% sensitivity and 67% specificity when deployed in rural Thai clinics, leading to a systematic remediation protocol that involved local data collection, transfer learning and automated performance-based rollback mechanisms [4]. These examples illustrate the need for the FDA framework to require ongoing post-deployment monitoring, predetermined adaptation procedures, and a tiered approach to change management based on whether they are minor, moderate, and significant model modifications [4].

B. European Medicines Agency (EMA)

The scope of the EMA's approach to AI regulation is considerably broader than the FDA's, explicitly covering the whole product lifecycle from early discovery to postmarket surveillance [4,14]. The AI Work Plan of the EMA, developed in collaboration with the Heads of Medicines Agencies (HMA) and valid until 2028, sets out risk-tiered explainability requirements and had a milestone date of March 2025 for its first qualification opinion for a clinical trial methodology with AI components as part of the clinical trial's design [4]. Moreover, the EU AI Act, which came into force in August 2024, classifies pharmaceutical artificial intelligence systems as high-risk and imposes conformity-assessment obligations and strengthened data-protection requirements under the General Data Protection Regulation. (GDPR) [4]. AI capacity building, infrastructure and methodology development across the European medicines regulatory network is structured by the HMA/EMA Big Data Steering Group and its associated Clusters of Excellence [5].

C. China National Medical Products Administration (NMPA)

The NMPA has taken a more aggressive, lifecycle approach to regulating AI, covering applications from target discovery through postmarket surveillance, and requiring mandatory algorithm registration in a national database and source code inspection a much more prescriptive position than the FDA or EMA [4,15]. China's regulatory strategy emphasizes sovereignty over health data, requiring extensive local validation using Chinese population datasets to address concerns about genetic and environmental differences that may affect model generalizability [4]. In addition to this technical lag, successive Five-Year Plans issued by NMPA and other government departments have promoted the integration of AI, big data, and blockchain technologies into smart drug regulation, including a national adverse-drug-reaction monitoring sentinel system [5].

D. Pharmaceuticals and Medical Devices Agency (PMDA), Japan

The PMDA has developed what many reviewers call the most granular framework among major regulators for adaptive, continuously learning artificial intelligence systems, with defined categories of AI adaptation, formal "change protocols" specifying permissible model evolution, sandbox environments for testing adaptive algorithms before deployment, and detailed version-control and rollback requirements [4]. As opposed to the FDA and EMA, the PMDA has not released a single consolidated plan for its AI reforms. Instead, Japan's Ministry of Health, Labor and Welfare funds specific research grants to explore the use of AI in regulatory science, a more decentralized, project-based approach to capacity building [5].

E. International Council for Harmonization (ICH)

The ICH has started to address AI and model-informed drug development (MIDD) in several guideline initiatives, including the M15 guideline on general principles for model-informed drug development and reflection papers exploring implications of AI for quality, stability, and patient-focused drug development [2,5]. But progress toward globally harmonized AI-specific standards those regarding terminology, minimum validation datasets and change-management practices has been relatively slow, a reflection of the various regulatory philosophies documented across FDA, EMA, NMPA and PMDA[4].

VII. COMPARATIVE ANALYSIS OF GLOBAL REGULATORY LANDSCAPE

Table 1 provides a high-level summary of the key structural differences across the four major regulatory structures discussed above, and Figure 4 offers a qualitative heat-map comparison of regulatory stringency over six dimensions: lifecycle scope, explainability requirements, validation rigor, data-localization requirements, accommodation of continuous learning, and transparency mandates.

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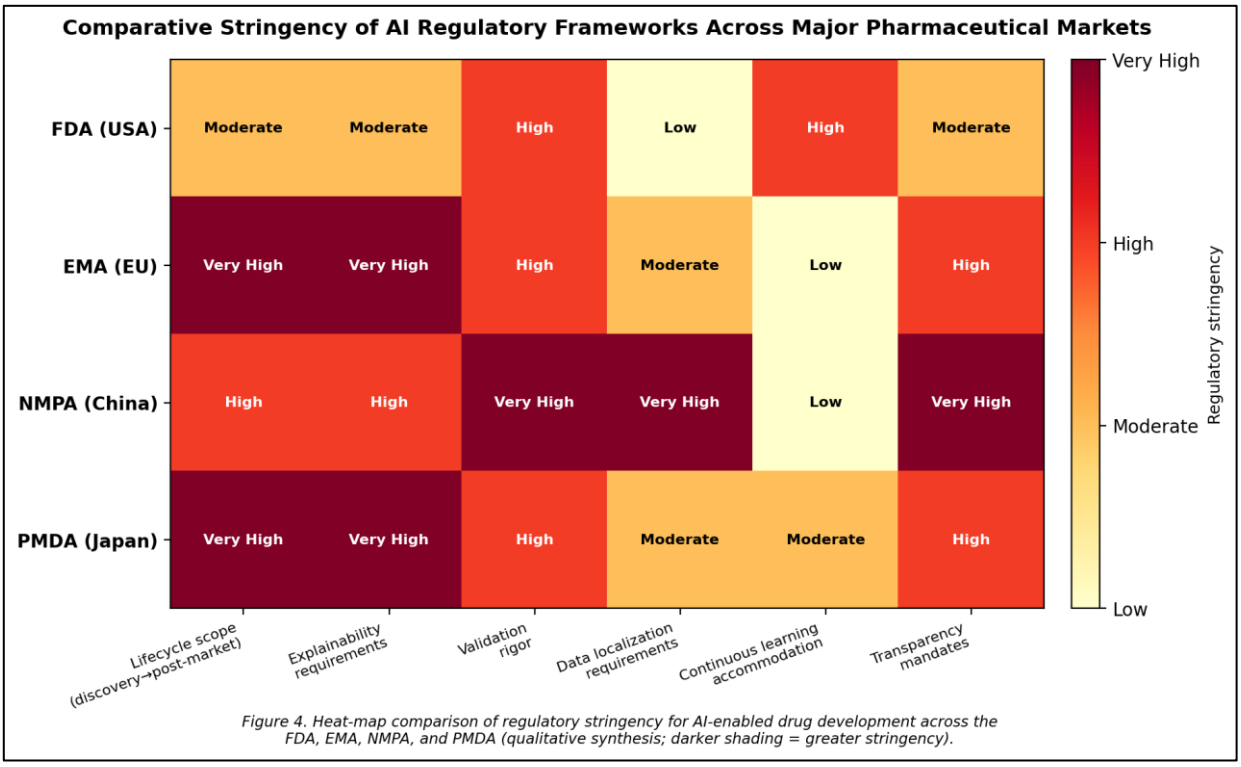

Figure 4. Heat-map comparison of regulatory stringency for AI-enabled drug development across the FDA, EMA, NMPA, and PMDA (qualitative synthesis; darker shading = greater stringency).

Table 1. Comprehensive Comparison of AI Regulatory Frameworks in Major Pharmaceutical Markets.

Feature	FDA (USA)	EMA (EU)	NMPA (China)	PMDA (Japan)
Scope	Regulatory decision-making only	Complete product lifecycle	Primarily devices, expanding to pharma	Comprehensive, phase-specific
Discovery-phase coverage	Excluded	Included	Limited, evolving guidance	Included, detailed requirements
Risk stratification	Three-tier (high/medium/low)	Five-level proportionate approach	Binary (high/low) classification	Multi-tier with subcategories
Explainability requirements	General principles, risk-based	Explicit, tied to risk level	Technical validation focus	Detailed standards, mandated tools
Data requirements	Emphasis on US-relevant data	EU population representation required	Chinese population data mandatory	Japanese bridging-study data needed
Continuous learning	Not explicitly addressed	Locked algorithms preferred	Prohibited without re-approval	Detailed adaptive-AI framework
Postmarket monitoring	Limited specific guidance	Mandatory for high-risk reporting	Centralized database required	Comprehensive, retraining required
Typical review timeline	6–10 months	12–15 months	12–18 months	9–12 months

These differences pose substantive challenges for multinational pharmaceutical companies developing integrated AI platforms for global deployment. Data-sovereignty and localization requirements – particularly strong in China – compete in some locations with the intellectual-property protections preferred in other jurisdictions. Smaller sponsors with limited regulatory-affairs bandwidth may find it difficult to manage simultaneously diverging explainability, validation, and reporting obligations [4]. International coordination efforts include the working group of the G7 Digital and Technology Ministers and the International Medical Device Regulators Forum (IMDRF). Mutual-recognition principles and common technical documentation standards have been proposed but effective harmonization remains at an early stage [4]. In general, the commonality of validation stringency is the most consistent factor across these comparative studies, and lifecycle scope and data-localization requirements the most divergent — suggesting that cross-agency harmonization efforts may be most effective in the near-term if they focus on shared technical validation standards, rather than on reconciling inherently distinct philosophies around data sovereignty and product-lifecycle oversight [4].

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VIII. AI IN PHARMACOVIGILANCE AND SAFETY SURVEILLANCE IN POST MARKETING

AI is also increasingly used to monitor postmarket safety, in addition to premarket development. The FDA's Center for Drug Evaluation and Research is employing supervised machine learning and natural language processing to automate the classification of adverse-event reports submitted to the FDA Adverse Event Reporting System (FAERS), to facilitate review and to direct expert attention to the most informative cases [5]. The FDA's Sentinel System has been fully operational since 2016 and complements FAERS by proactively tracking adverse events associated with regulated products across a distributed network of electronic health record data sources, and its planned five-year strategy has emphasized deeper integration of NLP and ML to extract safety-relevant features from unstructured clinical text [5,21].

Similar initiatives are underway internationally. For instance, Swissmedic's AI-based literature-search engine LiSA automatically identifies adverse drug reactions and assesses the relevance of the safety literature and the Uppsala Monitoring Center of the World Health Organization has developed the AI-based drug-coding engine WHODrug Koda to accelerate the coding of medicinal products described in adverse-event reports [5]. The growing sophistication of AI used for pharmacovigilance signal detection includes causal-inference approaches, such as InferBERT, which combines transformer-based language modeling with formal causal-inference methods [5,22].

However, reviewers warn that even with such advances, AI-powered safety surveillance suffers from the same data quality and representativeness issues that challenge AI more generally: reporting biases, incomplete case narratives, and demographic underrepresentation in adverse-event databases can all be perpetuated into AI-derived safety signals unless explicitly addressed using bias-assessment protocols [4,5].

IX. OBSTACLES AND LIMITATIONS

Despite significant advances, a number of cross-cutting challenges still limit the safe and effective use of AI in drug development and regulatory decision-making. Fig. 5. Overview of eight challenge domains emerged from the reviewed literature.

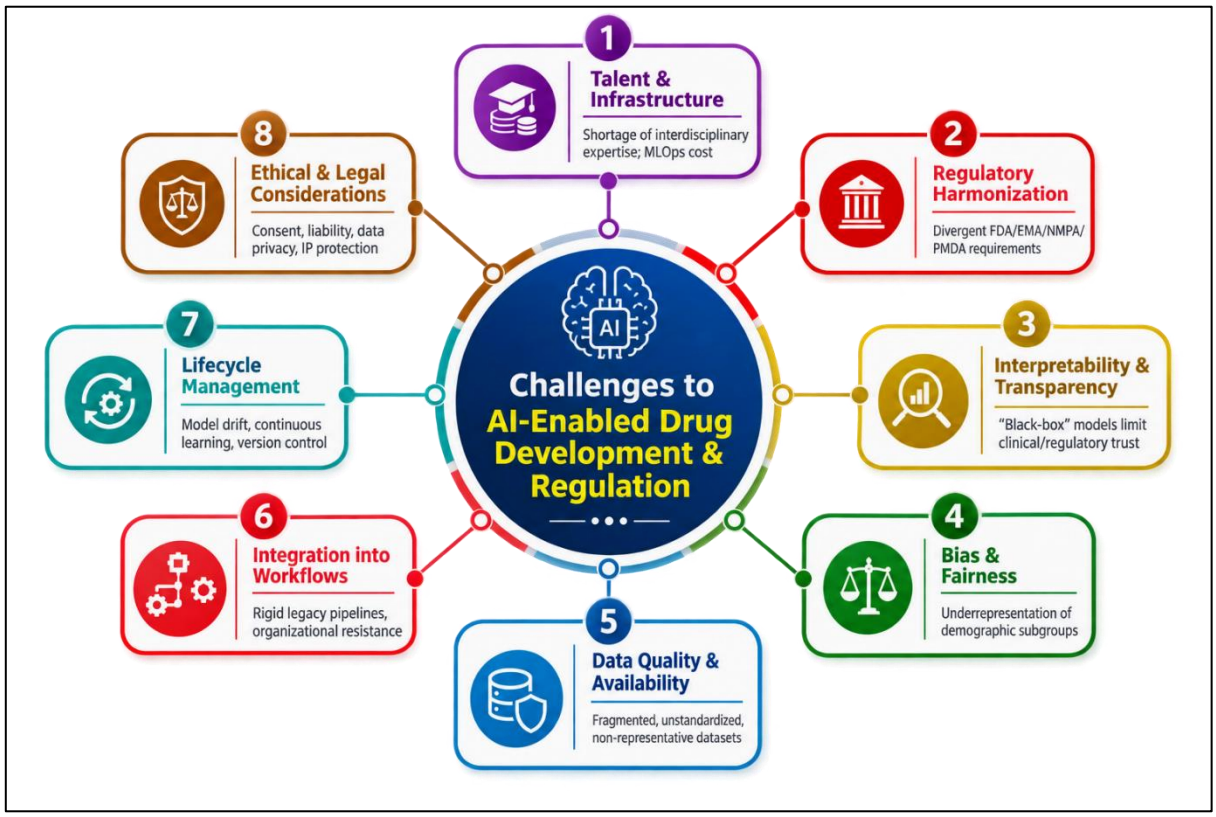

Fig 5 Principal Challenges Limiting the Adoption of Artificial Intelligence in Global Drug Development and Regulatory Decision-Making, Synthesized from Current Literature [1–5].

A. Data Quality, Availability and Biase

AI models need lots of good, representative training data, but biomedical data is often fragmented, inconsistently coded, and unevenly distributed across demographic groups and disease areas [1,3]. Systematic bias can arise when the resulting models exhibit systematic bias when training datasets overrepresent specific populations. A widely-cited example is an algorithm used to manage population health that was found to systematically underestimate illness severity in Black patients, limiting their access to care-management programs [4,18]. Addressing these risks requires rigorous fairness assessments, inclusive data collection practices, and explicit linkage of AI validation requirements

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to existing diversity-in-clinical-trials initiatives, such as FDA's Diversity Action Plans [4,19].

B. Explainability and the 'Black Box' Problem

Many high-performing deep learning models are functionally opaque, making it difficult for regulators, clinicians, and sponsors to understand the basis for a given prediction [1,3,5]. Explainability tools like SHapley Additive exPlanations (SHAP) and Local Interpretable Model-agnostic Explanations (LIME) can be used to show that a model's predictions are consistent with existing biological knowledge. However, full explainability is computationally expensive to implement, which makes it impractical for real-time applications on complex data such as medical images [4].

C. Regulatory Harmonization and Resource Imbalances

As discussed in Section 7, significant disparities among key regulatory regimes complicate multinational drug development programs and may impose excessive burdens on smaller sponsors without the regulatory-affairs infrastructure to navigate diverging jurisdictional requirements, possibly resulting in concentration of AI-enabled drug development within large, well-resourced organizations [4].

D. Workforce and Infrastructure Preparedness

The effective use of AI in drug regulation demands a blend of skills in data science, computer science, pharmacology and regulatory affairs, a combination of expertise not readily available in either industry or regulatory agencies [3,5]. The demands on resources for the machine-learning-operations (MLOps) infrastructure needed for continuous model monitoring, and the cybersecurity requirements for processing large-scale health data are out of reach for many organizations [4,5].

E. Lack of Universal Standards

At present, there is no international standard for the methodology of data exchange or validation related to AI in drug regulation. However, the Danish Medicines Agency's key considerations for static AI/ML algorithms in GxP settings, among other national initiatives, provide early templates that could be used to inform broader international standard-setting efforts [5].

X. DIRECTIONS FOR THE FUTURE

A number of trends are converging that are likely to shape the next phase of AI-enabled drug development and regulation. First, the scope of regulation should be expanded beyond applications in regulatory decision-making to more explicitly cover discovery-phase and operational AI, adopting the more comprehensive lifecycle models already adopted by the EMA and NMPA [4]. Second, bias-mitigation and demographic-subgroup validation requirements will likely be more explicit and formally tied to existing clinical-trial diversity frameworks [4,19]. Third, we expect tiered explainability standards to be codified, based on model risk classification and organizational capacity. This may be achieved by means such as SHAP-based global explanations for high-risk applications, and simpler feature-importance visualizations for lower-risk use cases [4].

Fourth, regulatory sandboxes and structured pilot programs for continuously learning, adaptive artificial intelligence (AI) systems are likely to proliferate. Early examples include PMDA's sandbox environments and the FDA's proposed regulatory-sandbox model for adaptive postmarket-surveillance algorithms [4]. Fifth, the integration of real-world evidence, supported by interoperability standards such as Fast Healthcare Interoperability Resources (FHIR), will likely become increasingly important for AI training and regulatory validation, particularly in rare diseases and oncology applications, where traditional randomized trials may not be feasible [4]. Finally, it will be important to continue international harmonization efforts through organizations such as the ICH, the G7 Digital and Technology Ministers, and the IMDRF to reduce redundant compliance burdens for multinational drug development programs, while respecting the legitimate differences in data governance and patient protection by jurisdiction [4,5].

Emerging technical developments, including integration of multi-omics data, protein and biological "language" models, state-space model architectures that offer greater computational efficiency than transformers, and quantum machine learning for complex molecular modeling, are also likely to reshape the technological foundations of pharmaceutical AI over the coming decade [1,4]. But the realization of their translational value will depend as much on regulatory science and interdisciplinary collaboration, as on continued algorithmic innovation [1,3,5]

XI. CONCLUSION

Artificial intelligence has been widely adopted throughout the pharmaceutical value chain, from early target identification to post-market pharmacovigilance, and regulatory agencies across the world are actively developing frameworks to regulate its credible and safe use in the generation of evidence for the approval of drugs and biological products. The FDA's risk-based approach to credibility assessment, the EMA's lifecycle approach, the NMPA's data sovereignty model and the PMDA's detailed provisions on adaptive AI, together, demonstrate not only a common understanding of the transformative potential of AI, but also a substantial philosophical difference in how to manage that potential. Existing challenges—data quality and bias, model interpretability, regulatory harmonization, workforce readiness, and the absence of universal standards—will continue to influence the pace and equity of AI adoption in drug development. Ongoing interdisciplinary collaboration between regulators, industry, academia, and patient advocates will be needed to realize the transformative potential of AI while maintaining the safety, efficacy, and quality standards that support global drug regulation.

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