RESEARCH PAPER

Strategic Management and the Development of Emerging Technologies in the Pharmaceutical Industry: A Dynamic Capability Perspective

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ABSTRACT

Static strategic management in pharmaceutical innovation treats regulation as a fixed external constraint and innovation as an independent optimization problem, yet AI systems for drug discovery, biologics, and mRNA platforms evolve at speeds that render this separation untenable. This paper reframes strategy as dynamic orchestration—a system-level architecture that continuously aligns technological capabilities with non-negotiable regulatory demands under conditions of temporal uncertainty. Dual constraints of innovation velocity and regulatory legitimacy create persistent distribution shifts that static planning cannot resolve. Temporal misalignment is formalized as the central failure mode, manifesting in three distinct types that produce strategic obsolescence even when technical validation succeeds. A multi-level framework integrates micro-level portfolio decisions, meso-level capability reconfiguration, and macro-level ecosystem positioning to enable regulated innovation. Strategic synchronization mechanisms are specified with formal notation so that ML engineers and strategists can embed regulatory interfaces directly into development pipelines. The capability–regulation co-evolution model is articulated as a recursive feedback loop in which regulatory change triggers organizational reconfiguration, new capabilities enable novel AI technologies, and those technologies in turn shape subsequent regulatory adaptation. The framework extends Teece's dynamic capabilities by incorporating regulatory alignment as an endogenous system variable, offering actionable design principles for AI-first biopharmaceutical firms operating under FDA and EMA uncertainty.

Keywords: Dynamic orchestration, Temporal misalignment, Dual constraints, Capability–regulation co-evolution, Pharmaceutical R&D, Regulatory alignment, Ecosystem positioning.

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INTRODUCTION

Machine learning systems for pharmaceutical R&D—including AI-driven drug discovery, biologics design, and mRNA platform optimization—are advancing at unprecedented speed, yet strategic management scholarship has not fully incorporated the regulatory realities that govern their deployment. Teece conceptualized dynamic capabilities as sensing, seizing, and transforming [1], but in the pharmaceutical AI context a fourth dimension—regulatory alignment—becomes necessary. Billinger *et al*. demonstrated that search across multiple technology platforms requires distinct capability configurations in pharmaceutical R&D [2], yet their analysis did not explicitly model the FDA's emerging technology framework as a co-evolutionary driver. Parida *et al*. reviewed the literature on digitalization and dynamic capabilities for sustainable business model innovation [3], underscoring the need to integrate external institutional pressures, but stopped short of specifying orchestration architectures under binding regulatory timelines.

The core problem is that static strategic planning assumes stable regulatory pathways, linear R&D timelines, independent optimization of innovation and compliance, and generalization from technical validation to regulated deployment. These assumptions collapse when AI model iterations occur on weekly timescales while FDA/EMA review cycles span years [4, 5]. Jacobides *et al*. established the foundations of ecosystem theory that explain why AI-first biopharmaceutical firms must orchestrate beyond firm boundaries [6], yet existing frameworks leave unfilled the explicit treatment of temporal misalignment and capability–regulation co-evolution. Behler's review of neural network potentials and Bartók *et al*.'s unification of materials and molecular modeling illustrate the rapid technical progress [7, 8], but neither addresses the regulatory lag that renders such models strategically obsolete before approval.

Cunningham *et al*. document how principal investigators already struggle with coordination in public-private pharmaceutical partnerships [9]; AI acceleration intensifies these inhibiting factors. Pesqueira and Sousa show that big-data analytics and dynamic capabilities operate in pharmaceutical ESG programs [10], while Chatzifoti *et al*. highlight knowledge management challenges between IT and regulatory functions [11]. Singh *et al*. call for

reimagining drug regulation in the AI era [12], and Jones *et al.* emphasize platform technologies require active regulatory and ecosystem management [13]. Goswami *et al.* identify antecedents of AI adoption in the Indian pharmaceutical sector constrained by regulatory uncertainty [14], and Nippa *et al.* illustrate how digitalisation accelerates compound synthesis yet encounters regulatory bottlenecks [5].

This study therefore develops a conceptual framework that (i) reframes strategy as dynamic orchestration under dual constraints, (ii) formalizes temporal misalignment as the central failure mode, (iii) presents a multi-level orchestration architecture, (iv) specifies synchronization mechanisms, and (v) models capability–regulation co-evolution. The contribution is both strategic and engineering-relevant: managers receive a system architecture that treats compliance as an endogenous design variable, while ML engineers obtain explicit guidance on where their systems must interface with regulatory processes.

STRATEGY AS DYNAMIC ORCHESTRATION: REFRAMING THE CORE FUNCTION

Dynamic Orchestration is a system-level architecture comprising three functional components—sensing, seizing, and transforming—operating in a continuous feedback loop that explicitly incorporates regulatory signals as first-class inputs rather than exogenous constraints. Sensing detects emerging AI capabilities and regulatory changes through integrated horizon-scanning routines. Seizing reconfigures R&D portfolios, compliance processes, and partnership structures in real time. Transforming restructures organizational boundaries and internal routines to embed regulatory alignment into core operations.

Teece originally conceptualized dynamic capabilities as sensing, seizing, and transforming [1], but pharmaceutical AI demands explicit regulatory embedding because compliance is not a separable activity. Billinger *et al.* showed that pharmaceutical R&D already requires distinct capability configurations for multi-platform search [2], yet their model assumes regulatory stability that no longer holds. Jacobides *et al.* supply the ecosystem lens [6] necessary for macro-level positioning, but do not articulate the orchestration mechanisms required when one ecosystem actor (the regulator) imposes binding temporal constraints.

Figure 1 depicts the architecture as three interconnected boxes arranged in a cycle: Sensing receives inputs (AI technology signals + regulatory signals + market signals) and feeds Seizing, which in turn feeds Transforming; Transforming loops back to Sensing with updated capability states and ecosystem position data.

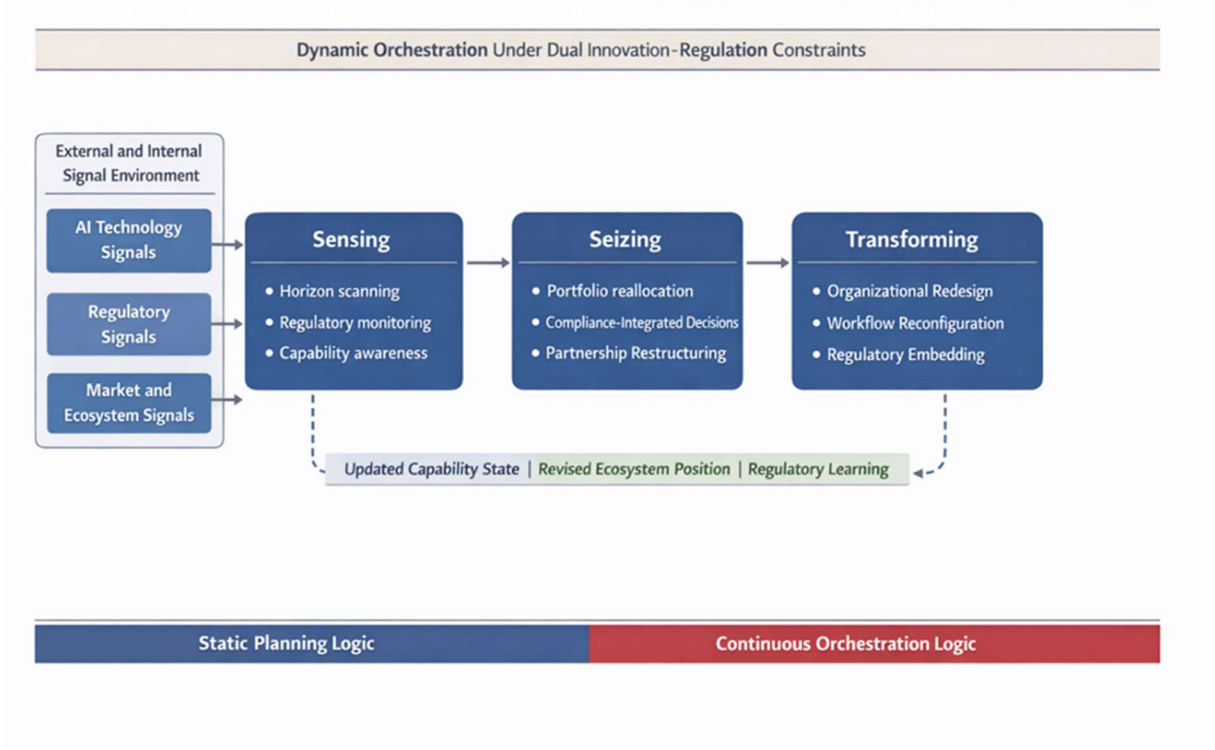

Figure 1. Dynamic Orchestration Architecture for AI-Driven Pharmaceutical Innovation Under Regulatory Uncertainty

This reframing shifts strategy from static planning (fixed goals, stable resource allocation) to continuous orchestration under uncertainty. Parida *et al.* demonstrate that digitalization necessitates dynamic capabilities precisely because static models cannot accommodate institutional change [3]. The architecture therefore elevates regulatory alignment from an external constraint to an internal system variable, enabling firms to maintain innovation velocity without sacrificing legitimacy.

DUAL CONSTRAINTS: INNOVATION VS. REGULATION

Dual Constraints refer to the simultaneous and non-substitutable pressures of (a) innovation velocity (rapid AI capability development) and (b) regulatory legitimacy (FDA/EMA approval and post-market surveillance). Unlike typical strategic trade-offs, these constraints operate on

incompatible timescales and cannot be resolved by optimization within a single dimension.

Innovation velocity is illustrated by Bilotta *et al*.'s documentation of next-generation AI for pharmaceutical research [4] and Nippa *et al*.'s description of accelerated compound synthesis through digitalisation [5]. Regulatory legitimacy, however, follows multi-year cycles that impose non-negotiable external shifts [12]. Jones *et al*. show that platform technologies generate value only when firms actively manage both dimensions [13].

Static strategic management fails because it treats regulation as a fixed constraint rather than a co-evolving variable. Cunningham *et al*. identify coordination challenges in pharmaceutical partnerships that are exacerbated under dual constraints [9]. Pesqueira and Sousa illustrate how dynamic capabilities already address ESG integration in pharmaceuticals [10], yet do not extend the logic to regulatory–innovation duality. Chatzifoti *et al*. highlight knowledge integration gaps between technology and regulatory functions [11], while Goswami *et al*. note that AI adoption antecedents remain constrained by regulatory uncertainty [14].

The duality creates a regulated deployment distribution shift: the conditions under which an AI system is technically validated differ fundamentally from the conditions under which it must operate post-approval. This shift is institutionally imposed and cannot be mitigated by retraining alone. Dynamic orchestration therefore becomes the only viable strategic response, treating both constraints as endogenous to the system architecture.

Temporal Misalignment as a Central Failure Mode

Temporal misalignment represents a foundational and under-theorized source of failure in AI-driven pharmaceutical innovation, arising not from deficiencies within individual subsystems but from divergences in their respective rates of change. AI technology development, regulatory approval processes, organizational capability building, and market adoption each evolve according to distinct temporal logics, governed by different constraints, incentives, and epistemic structures. When these subsystems become desynchronized, the resulting lack of temporal coherence produces strategic breakdowns even in cases where each subsystem performs optimally when evaluated in isolation. The central problem, therefore, is not inefficiency but incompatibility in temporal dynamics.

Temporal Misalignment is a divergence in rates of change across interdependent subsystems—AI technology development, regulatory approval, organizational capability building, and market adoption—that produces strategic failure even when each subsystem performs optimally in isolation.

This definition shifts the analytical focus from localized optimization to systemic coordination. It suggests that improving any single subsystem—faster AI models, more rigorous regulatory review, stronger capabilities, or more responsive markets—does not resolve failure if their temporal trajectories remain misaligned. Instead, performance becomes constrained by the slowest or most structurally rigid subsystem, while the fastest-moving subsystem generates instability by outpacing the rest. Temporal misalignment therefore operates as a structural bottleneck on innovation, limiting the ability of firms to convert technological progress into approved, deployable, and economically viable outcomes.

Three analytically distinct types of temporal misalignment emerge, each corresponding to a specific configuration of rate divergence and each generating a characteristic pattern of failure [15].

Type 1 (AI–Regulation Rate Gap) arises from the fundamental disparity between the rapid iteration cycles of AI systems and the comparatively slow, procedural timelines of regulatory approval. Machine learning models evolve through continuous retraining, dataset expansion, and architectural refinement, often on weekly or monthly cycles. Regulatory processes, by contrast, require stability, reproducibility, and extensive validation, unfolding over 10–24 month horizons [16]. This temporal gap produces a structural paradox: systems that are validated at submission may no longer reflect the most current or best-performing version of the technology at the point of approval. The result is not merely delay but a decoupling between regulatory certification and technological relevance, which undermines both the value of approval and the incentives to seek it [4].

Type 2 (Capability–Technology Lag) emerges within the firm, where the rate of technological advancement exceeds the pace of organizational adaptation. While AI capabilities scale rapidly through computational improvements and data availability, organizational capabilities—such as cross-functional integration, regulatory expertise, data governance, and workflow redesign—develop more slowly due to their dependence on learning, coordination, and institutional change. This creates a persistent lag in which firms possess technically advanced models but lack the capacity to deploy them effectively and compliantly][15-24]. The consequence is a form of constrained innovation, where technological potential remains unrealized because the organizational system is not yet configured to absorb and operationalize it [11, 14].

Type 3 (Market–Regulation Asynchrony) manifests at the interface between firms and their external environment, where market dynamics accelerate independently of regulatory development. Investor expectations, competitive entry, and narratives of technological disruption can rapidly intensify demand for AI-enabled solutions, pushing firms toward early commitment and aggressive scaling. However, regulatory frameworks often lag behind these developments, remaining incomplete, ambiguous, or in flux. This creates conditions in which firms invest heavily in technologies that lack clearly defined approval pathways, leading to overextension and exposure to regulatory uncertainty. In such contexts, strategic positioning becomes decoupled from institutional feasibility, increasing the risk of stranded investments and failed commercialization [12, 13].

Existing literature has recognized the importance of adaptability under such conditions but has not fully theorized the temporal structure of these failures. Billinger *et al*. demonstrate that pharmaceutical R&D environments require dynamic capabilities when uncertainty and discontinuity are present [2], yet their analysis does not differentiate between distinct forms of temporal divergence. Similarly, Parida *et al*. emphasize dynamic capabilities in the context of digital transformation [3], but treat temporal dynamics as implicit rather than central. As a result, both perspectives highlight the need for adaptation without providing a framework for diagnosing the specific temporal configurations that give rise to failure [25-33].

This limitation becomes particularly evident when

considering the inadequacy of static planning approaches. Traditional planning assumes synchronized, linear progression across subsystems, enabling coordination through sequencing and forecasting. Under conditions of temporal misalignment, however, such assumptions break down. Subsystems evolve asynchronously, rendering fixed plans obsolete and creating cascading coordination failures. Strategic effectiveness therefore depends not on prediction but on the continuous management of temporal divergence [34-44].

The typology developed here provides a diagnostic vocabulary that allows both strategists and ML engineers to identify which subsystem rate mismatch is driving failure in a given context. By distinguishing between AI–regulation gaps, capability–technology lags, and market–regulation asynchronies, the framework enables more precise intervention. Rather than pursuing generalized alignment, firms can target the specific temporal interface where divergence is most consequentiall [45-50].

Without explicit recognition of temporal misalignment, even advanced dynamic capabilities frameworks remain incomplete for regulated AI environments. They describe how firms adapt but do not fully explain why adaptation fails when subsystems evolve at incompatible speeds. By foregrounding temporal divergence as the primary source of strategic breakdown, this framework reorients analysis toward the synchronization problem at the core of AI-driven innovation [51-56].

A Multi-Level Framework for Regulated Innovation Under Uncertainty

Addressing temporal misalignment requires a framework that operates simultaneously across multiple levels of analysis, integrating decision-making, capability development, and institutional alignment into a coherent system. The proposed multi-level framework conceptualizes regulated innovation as a vertically structured yet dynamically interconnected process, in which actions at one level shape and are shaped by developments at others. Rather than treating these levels as independent, the framework emphasizes their reciprocal interaction under conditions of uncertainty.

At the micro level, the focus is on R&D portfolio decisions in environments characterized by AI-driven uncertainty. Firms must continuously evaluate the relative viability of AI-enabled and traditional development pathways, not only in terms of technical performance but also with respect to regulatory clarity and integration complexity. This requires a shift away from deterministic planning toward more flexible decision logics that accommodate uncertainty and reversibility. Investments are structured to preserve optionality, allowing firms to adapt as new information emerges about technological feasibility, regulatory expectations, and market conditions. Decision-making at this level becomes inherently dynamic, reflecting the need to manage evolving risk rather than optimize against fixed assumptions.

The meso level centers on the reconfiguration of organizational capabilities and the integration of diverse knowledge domains. Effective AI deployment in regulated environments depends on the coordination of machine learning expertise, domain-specific scientific knowledge, and regulatory understanding. This necessitates the deliberate construction of cross-functional teams and the institutionalization of mechanisms for knowledge transfer and capability development. Capability pipelines are developed not only for technical domains such as mRNA and biologics but also for regulatory navigation and compliance management. Over time, these pipelines enable the organization to reduce the lag between technological advancement and deployment readiness, thereby addressing one of the core sources of temporal misalignment.

At the macro level, the framework extends beyond the firm to encompass regulatory alignment and ecosystem positioning. Firms must actively engage with evolving regulatory programs, interpret emerging guidelines, and anticipate shifts in institutional expectations. At the same time, they must position themselves within a broader ecosystem that includes large pharmaceutical companies, AI-first biotechnology firms, contract research organizations, and regulatory bodies. Strategic positioning within this ecosystem influences access to resources, information, and legitimacy, all of which are critical for navigating uncertainty. Alignment at this level is therefore not passive but actively constructed through engagement, signaling, and coordination with external actors [6, 12].

Crucially, these three levels are not independent layers but mutually reinforcing components of a single system. Decisions made at the micro level shape capability requirements at the meso level, while both are constrained and enabled by conditions at the macro level. Conversely, changes in regulatory frameworks or ecosystem dynamics feed back into organizational capabilities and R&D priorities. This vertical integration ensures that the framework captures not only the structure of innovation but also its dynamic evolution over time.

By integrating these levels, the framework provides a comprehensive approach to managing regulated innovation under uncertainty. It moves beyond isolated interventions to address the systemic nature of temporal misalignment, offering a structured way to coordinate across domains with inherently different temporal dynamics. In doing so, it complements the typology developed in Section 4 by providing the organizational architecture through which identified misalignments can be actively managed and mitigated.

Figure 2 visualizes three horizontal layers connected by vertical integration arrows (Micro → Meso → Macro) and feedback loops from Macro back to Micro via regulatory signals. Pesqueira and Sousa illustrate meso-level dynamic capabilities in pharmaceutical programs [10], while Jacobides *et al*. supply the macro-ecosystem logic [6]. The framework's contribution is the explicit vertical coupling: micro decisions are evaluated on their contribution to meso capability depth and macro regulatory influence.

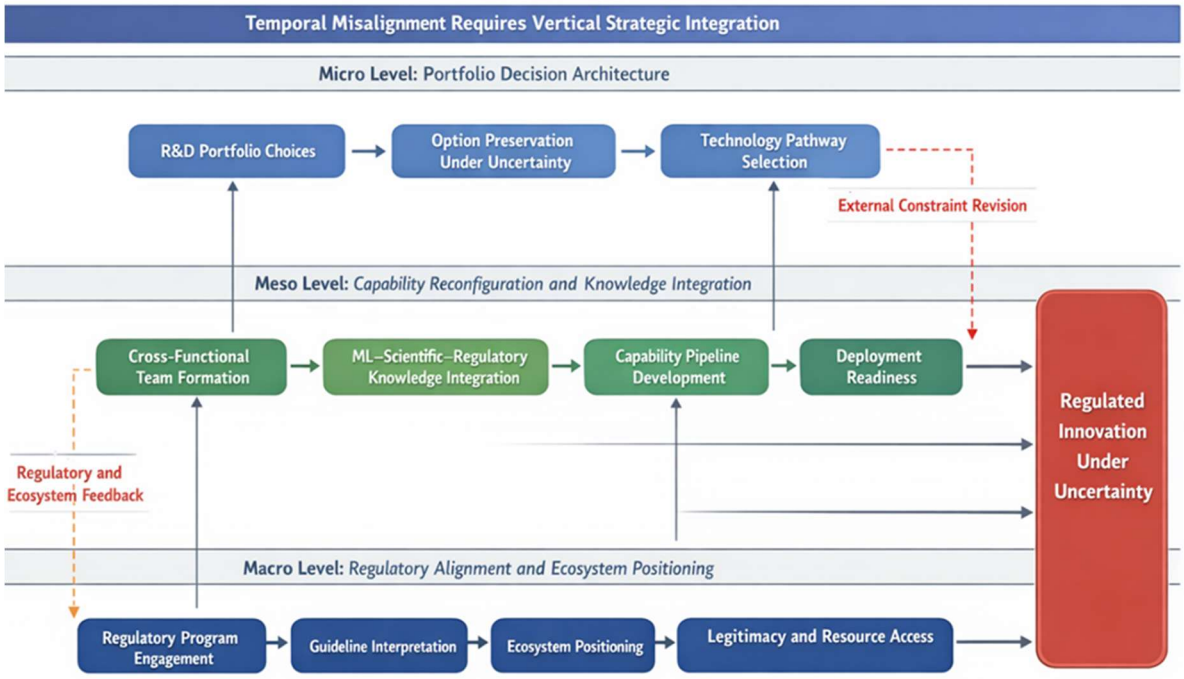

Figure 2. Temporal misalignment vertical strategic integration

This architecture ensures that innovation under dual constraints is not fragmented but systemically aligned.

Strategic Synchronization Mechanisms

Strategic synchronization mechanisms constitute the operational layer through which orchestration architectures are translated into coordinated, repeatable organizational routines. Rather than remaining abstract design principles, these mechanisms embed alignment directly into decision processes, capability development, and inter-organizational coordination, ensuring that technological advancement and regulatory evolution do not diverge in destabilizing ways. Each mechanism addresses a distinct form of misalignment while collectively reinforcing systemic coherence across the innovation lifecycle.

Regulatory embedding introduces alignment at the earliest stages of decision-making by integrating regulatory pathway analysis into every critical milestone of AI development. Instead of treating compliance as a downstream validation step, this mechanism restructures decision logic such that regulatory feasibility becomes an intrinsic condition of technological progression. As a result, strategic choices are continuously filtered through regulatory viability, preventing the accumulation of latent incompatibilities that would otherwise surface at later stages. In doing so, regulatory embedding directly resolves Type 1 misalignment by collapsing the separation between innovation and compliance domains and transforming regulatory knowledge into a generative constraint rather than an external barrier [2, 12].

A related but distinct challenge emerges from the temporal imbalance between technological advancement and organizational readiness. Adaptive capability pipelines address this issue by ensuring that capability development unfolds in parallel with technological innovation rather than lagging behind it. This mechanism reframes capability building as a dynamically coupled process in which organizational learning, infrastructure development, and talent acquisition evolve in continuous interaction with emerging technological demands. The result is a synchronized trajectory in which firms avoid the structural bottlenecks that arise when advanced technologies outpace the capabilities required to implement, govern, and scale them effectively. Through this continuous co-evolution, adaptive capability pipelines mitigate Type 2 misalignment by stabilizing the relationship between innovation velocity and absorptive capacity [11, 14].

Even under conditions of improved alignment, temporal discrepancies between regulatory processes and AI development cycles remain unavoidable. Temporal buffering responds to this structural reality by deliberately maintaining strategic reserves—organizational, financial, and temporal—that absorb fluctuations in the relative pace of these domains. Rather than attempting to eliminate misalignment entirely, this mechanism acknowledges its persistence and focuses on controlling its magnitude and impact. By creating tolerance margins within which divergence can occur without triggering systemic disruption, temporal buffering transforms misalignment from a critical failure condition into a manageable operational parameter. In this sense, it plays a crucial role in mitigating Type 3 misalignment by preserving strategic flexibility under conditions of uncertainty and regulatory lag [13].

Beyond the boundaries of the focal firm, synchronization increasingly depends on the coordinated behavior of a broader ecosystem of actors, including partners, regulators, and complementary innovators. Ecosystem orchestration extends synchronization mechanisms into this distributed

environment by structuring how costs, risks, and informational burdens are allocated across participants. Rather than centralizing control, this mechanism enables coordinated interdependence, where multiple actors collectively sustain alignment through shared constraints and negotiated responsibilities. This distributed approach not only reduces the burden on any single organization but also enhances system-level resilience by embedding alignment across networked relationships rather than within isolated entities [6].

Table 1 consolidates the article's synchronization mechanisms by linking each mechanism to the misalignment type it addresses, the level at which it operates, and the strategic effect it is expected to produce.

Table 1. Strategic Synchronization Mechanisms for Managing Temporal Misalignment in AI-Driven Pharmaceutical Innovation

Synchronization Mechanism	Primary Target of Intervention	Misalignment Type Addressed	Level of Operation	Core Strategic Logic	Organizational Implementation	Expected Strategic Effect
Regulatory Embedding	AI development milestones and portfolio gating decisions	Type 1: AI–Regulation Rate Gap	Micro / Meso	Regulatory feasibility is incorporated at the point of model and project progression rather than deferred to downstream review	Regulatory pathway review is inserted into milestone design, model validation checkpoints, documentation standards, and decision gates	Reduces late-stage incompatibility, lowers obsolescence risk, and aligns innovation trajectories with approval logic
Adaptive Capability Pipelines	Internal organizational readiness relative to AI capability growth	Type 2: Capability–Technology Lag	Meso	Capability development must evolve in parallel with technological advancement rather than react after technical breakthroughs occur	Cross-functional teams, regulatory-aware data governance, translational workflows, and ongoing talent development are built as standing organizational capacities	Narrows the gap between technical invention and compliant deployment readiness
Temporal Buffering	Timing instability across regulatory, technological, and market domains	Type 1 and Type 3	Micro / Macro	Misalignment cannot always be eliminated, so firms require reserves that absorb timing shocks without forcing strategic breakdown	Parallel pathways, slack time, budgetary reserves, staged commitments, and optionality-preserving project design are maintained intentionally	Converts timing volatility into a manageable operating condition rather than a catastrophic disruption
Ecosystem Orchestration	Distributed coordination across firms, regulators, CROs, and partners	Type 3: Market–Regulation Asynchrony	Macro	Alignment depends on coordinated interdependence across the wider innovation ecosystem, not only on	Shared standards, collaborative regulatory engagement, consortia, partnership design, and burden-	Increases legitimacy, distributes synchronization costs, and reduces exposure to stranded investments

				focal-firm efficiency	sharing arrangements are institutionalized	
Cross-Functional Synchronization Teams	Knowledge fragmentation between ML, scientific, and regulatory units	Type 2, with spillover to Type 1	Meso	Strategic alignment requires decision rights that bridge epistemic and organizational boundaries	Joint governance structures are formed in which ML engineers, domain scientists, and regulatory specialists evaluate progression together	Improves translation across domains and reduces organizational delay in regulated deployment
Regulatory Signal Monitoring	Early detection of evolving FDA/EMA expectations	Type 1 and Type 3	Macro / Meso	Firms need continuous institutional sensing because regulatory change is a moving input, not a static condition	Horizon-scanning routines, guidance tracking, pilot program participation, and systematic interpretation mechanisms are established	Enhances anticipatory adaptation and reduces surprise from institutional change

Taken together, these mechanisms reveal that synchronization is not a singular intervention but a layered and interdependent process. Regulatory embedding establishes alignment at the level of decision logic, adaptive capability pipelines sustain it through organizational development, temporal buffering stabilizes it under dynamic conditions, and ecosystem orchestration extends it across organizational boundaries. The underlying theoretical foundation for this integrated approach can be traced to the dynamic capabilities perspective articulated by David Teece, which emphasizes the continuous alignment of sensing, seizing, and reconfiguring activities in rapidly evolving environments [1]. What distinguishes the present framework, however, is the explicit operationalization of these principles into concrete synchronization mechanisms, thereby transforming abstract strategic theory into implementable organizational practice.

THE CAPABILITY–REGULATION CO-EVOLUTION MODEL

The capability–regulation co-evolution model is a recursive feedback loop: regulatory change triggers capability reconfiguration, new capabilities enable novel AI technologies, novel technologies create regulatory feedback, and regulatory adaptation induces further evolution.

Proposition 1 (Feedback Loop Structure) captures this cycle. Proposition 2 (Firm Heterogeneity) states that firms with higher orchestration capability proactively shape regulation via FDA programs; lower-orchestration firms remain rule-takers. Proposition 3 (Co-evolution Speed Matching) requires matching reconfiguration timescales to regulatory cycles; mismatch produces persistent misalignment.

Figure 3 shows the four-node loop with a dashed arrow from Firm Orchestration Capability to Regulatory Change representing Proposition 2 influence. Cunningham *et al*. [9] and Billinger *et al*. [2] ground capability lags; Jacobides *et al*. [6] establish ecosystem conditions for influence. The model supplies both explanatory power and prescriptive guidance for AI-enabled pharmaceutical strategy.

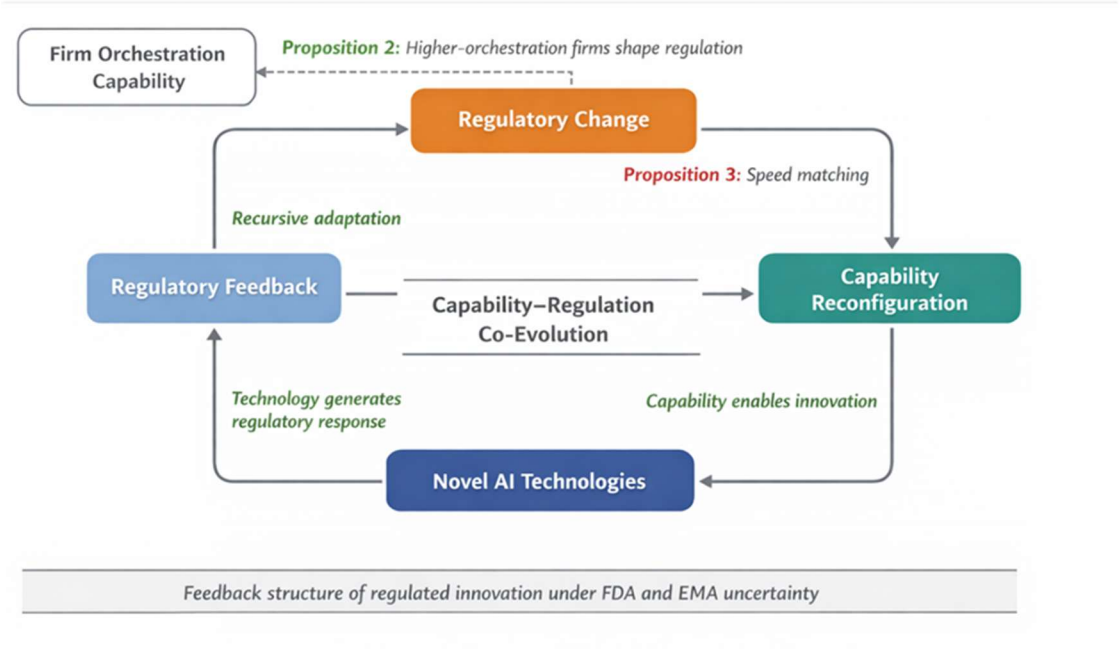

Figure 3. Capability-regulation co-evolution model in AI-first biopharmaceutical strategy

RELATION TO EXISTING STRATEGIC MANAGEMENT THEORIES

This framework extends Teece's dynamic capabilities [1] by incorporating regulatory alignment as an endogenous fourth dimension within the sensing-seizing-transforming cycle. Teece conceptualized dynamic capabilities as sensing, seizing, and transforming [1], yet the pharmaceutical AI context requires explicit treatment of regulation as a co-evolving system input rather than a background condition. Our dynamic orchestration architecture operationalizes this extension through formalized synchronization mechanisms and a multi-level structure that Teece's original formulation left implicit.

The framework also builds directly on Billinger *et al*.'s demonstration that search across multiple technology platforms in pharmaceutical R&D demands distinct capability configurations [2]. Billinger *et al*. showed that dynamic capabilities must be contextually adapted, but their analysis assumed regulatory stability that no longer exists under AI-driven innovation [2]. We address this gap by formalizing temporal misalignment as the central failure mode and by specifying how capability reconfiguration must occur in parallel with regulatory change.

Ecosystem theory receives further elaboration through Jacobides *et al*.'s foundations [6]. Jacobides *et al*. established that value creation in ecosystems depends on orchestration beyond firm boundaries [6], yet they did not model the binding temporal constraints imposed by a regulator. Our macro-level orchestration and ecosystem positioning component close this gap by treating regulatory bodies as active participants whose signals must be sensed and seized in real time.

Parida *et al*.'s review of digitalization and dynamic capabilities for sustainable business model innovation [3] similarly underscores the need to integrate external institutional pressures, but stops short of specifying orchestration architectures under dual innovation–regulation constraints. Our capability–regulation co-evolution model fills this void by articulating a recursive feedback loop with three explicit propositions.

While the resource-based view underpins much of the dynamic capabilities literature [1], it treats resources and capabilities as internally controllable. Our framework demonstrates that in regulated AI pharmaceutical environments, capabilities must co-evolve with external regulatory regimes that cannot be controlled, only orchestrated. Existing theories therefore leave two critical gaps unfilled: (i) explicit formalization of temporal misalignment across AI, regulatory, organizational, and market subsystems, and (ii) a capability–regulation co-evolution model that treats regulation as an endogenous driver of strategic architecture rather than an exogenous constraint. By addressing these gaps, the present framework advances strategic management theory from contingency-based adaptation toward engineered orchestration under non-negotiable institutional timelines.

IMPLICATIONS FOR MANAGERS AND POLICYMAKERS

Pharmaceutical managers must treat regulatory compliance as an orchestration input rather than a downstream constraint. This requires embedding regulatory pathway analysis into every AI model development milestone through the regulatory embedding mechanism we propose. Managers should build cross-functional synchronization teams that grant joint decision rights to ML engineers and regulatory affairs specialists, thereby resolving Type 2 capability–technology lag [11, 14]. Temporal buffering strategies—maintaining non-zero strategic reserves of time, budget, and parallel regulatory pathways—become essential for absorbing Type 1 and Type 3 misalignment shocks [2, [13].

For regulators (FDA and EMA), the framework implies the

design of adaptive regulatory pathways that explicitly recognize regulation as a co-evolutionary force. Regulators should accelerate pilot programs within the Emerging Technology Program and qualification procedures for AI-based biomarkers so that capability reconfiguration can match technology velocity [12]. By publishing draft guidances with clear synchronization points, regulators can reduce temporal misalignment and enable firms to seize opportunities rather than merely react.

Policymakers should fund capability-building initiatives alongside technology development grants. Public funding mechanisms must prioritize meso-level knowledge integration infrastructure (cross-functional teams and regulatory-aware datasets) rather than isolated AI research [9, 10]. Coordinated timelines between innovation funding agencies and regulatory bodies would directly mitigate market–regulation asynchrony [6 , 13]. Policymakers can also incentivize ecosystem orchestration by supporting consortia that distribute synchronization costs across Big Pharma, AI-first biotechs, CROs, and regulators.

Taken together, these implications shift managerial practice from static portfolio optimization to dynamic orchestration and shift public policy from rule-setting to co-evolutionary facilitation. Firms with superior orchestration capability will proactively shape regulatory evolution [1], while laggards remain rule-takers experiencing persistent misalignment. The framework therefore supplies both diagnostic criteria and actionable levers for managers and policymakers operating at the innovation–regulation frontier.

CONCLUSION

Static strategic management fails under the innovation–regulation duality because it assumes stable regulatory pathways, linear R&D timelines, independent optimization of innovation and compliance, and generalization from technical validation to regulated deployment. This paper has reframed strategy as dynamic orchestration—a system-level architecture that continuously senses AI capabilities and regulatory signals, seizes reconfiguration opportunities, and transforms organizational boundaries under non-negotiable external constraints.

The framework proceeds through dual constraints, a typology of three temporal misalignment failure modes, a multi-level (micro-meso-macro) orchestration structure, formalized strategic synchronization mechanisms, and a capability–regulation co-evolution model articulated via three propositions. By integrating sensing-seizing-transforming logic with ecosystem positioning and digitalization insights, the architecture fills critical gaps in existing strategic management theories.

For AI engineering practice and pharmaceutical strategy alike, the implications are immediate: regulatory pathways must be treated as first-class constraints coded into model development pipelines, cross-functional integration requires permanent architectural support, and temporal buffering must become standard design practice. Future empirical research should test the propositions through qualitative comparative case studies across AI-first biopharmaceutical firms, while technical work should develop regulatory-aware ML system architectures that implement the synchronization mechanisms we formalize. Ultimately, dynamic orchestration offers the conceptual and practical foundation for sustaining regulated innovation in an era when AI capability velocity permanently outpaces regulatory adaptation cycles.

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