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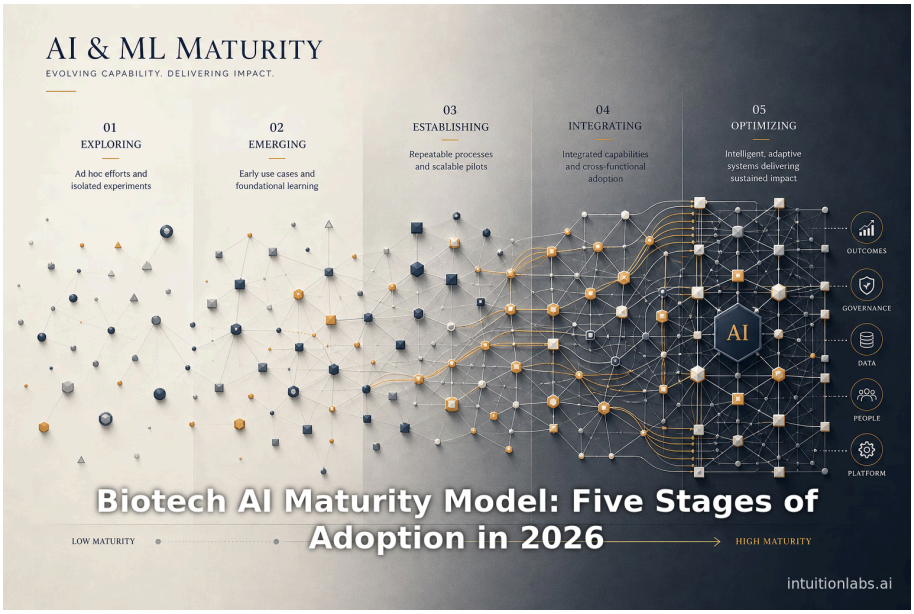
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Biotech AI Maturity Model: Five Stages of Adoption in 2026

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Executive Summary

Biotech and pharmaceutical organizations are adopting artificial intelligence (AI) at a pace that consistently outstrips their governance, data, and talent readiness. Surveys converge on the same pattern: **75%** of life-sciences executives say their companies began implementing AI within the past two years and **86%** plan to deploy AI tools within the next two years (axios.com), yet only **53%** have formal AI policies or standard operating procedures and just **51%** conduct regular audits (axios.com). This gap between enthusiasm and operational maturity is the reason a **biotech AI maturity model** matters: it gives R&D, quality, IT, and compliance leaders a shared vocabulary for describing how far along the adoption curve their organization actually sits, distinct from how far along it claims to be in a board deck.

This report synthesizes the published maturity frameworks most relevant to biotech and pharma, including the International Society for Pharmaceutical Engineering's (ISPE) GAMP AI Maturity Model for GxP (Good Practice) applications (ispe.org), Cradle.bio's five-level machine learning (ML) maturity ladder for biologics discovery, Axio BioPharma's Biomanufacturing AI Maturity Index (BAMI) (axiobiopharma.com), a Stanford-inspired four-stage enterprise model popularized by Sakara Digital (sakaradigital.com), and a generative AI (Gen AI) capabilities model published jointly by CGI and Roche authors in DIA's Global Forum (globalforum.diaglobal.org). It synthesizes these into a consolidated five-stage biotech AI maturity model spanning ad hoc and shadow use, localized pilots, governed programmatic adoption, enterprise integration, and autonomous or agentic systems.

The data show most biotech and pharma organizations remain clustered in the early stages. A 2025 survey of 16 of the top 20 pharmaceutical companies found **70%** of leaders call AI an "immediate priority" (rising to **85%** among top-20 firms) and more than **80%** are increasing AI budgets (fiercepharma.com), but Deloitte's fourth annual Life Sciences Outlook Survey of 280 C-suite executives found only **22%** of life-sciences leaders have successfully scaled AI and just **9%** report significant returns (deloitte.com). ZS's 2026 CDIO research of 115 pharma and biotech technology executives found **68%** cite neglected data quality and governance as the primary reason AI initiatives fail, and only about **40%** of pilots ever reach scaled deployment (zs.com).

A parallel and underappreciated risk sits beneath these adoption numbers: shadow AI, the unsanctioned use of consumer-grade AI tools outside governance channels. Wolters Kluwer's survey of more than 500 health professionals found **40%** had encountered unauthorized AI tools at work and **17%** had used them (fiercehealthcare.com), while an IBM-sponsored study found **80%** of American office workers use AI at work but only **22%** rely exclusively on employer-approved tools (ibm.com). KPMG defines shadow AI as systems "developed and deployed within an organization without explicit approval, oversight, or awareness from the central IT, compliance, or governance teams" (kpmg.com), a risk that is amplified in biotech by the presence of protected health information, trade secrets, and pre-competitive molecular data.

Maturity is not merely an internal metric; it is increasingly a regulatory expectation. The U.S. Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) has reviewed over **500** drug application submissions containing AI components between 2016 and 2023 and established a dedicated CDER AI Council in 2024 to coordinate policy (fda.gov). In the European Union, the EU AI Act imposes staged deadlines, including an application date of **2 December 2027** for high-risk systems under Annex III, as postponed by Regulation (EU) 2026/1744 (eur-lex.europa.eu). Whether a given AI application is high-risk depends on whether it falls within the Annex III use cases or the Annex I product legislation. Organizations that cannot demonstrate structured maturity, in the form of documented control design, validation levels, and data governance, will struggle to satisfy either regulator.

The report closes with case studies (Moderna's enterprise-wide generative AI rollout, Insilico Medicine's AI-discovered drug rentosertib entering Phase III trials, Bristol Myers Squibb's "predict first" strategy, and Novartis's responsible AI governance framework), a data-driven audit of adoption statistics, and forward-looking guidance on how biotech organizations can progress deliberately through the maturity stages rather than stalling in shadow use or perpetual pilot mode. PwC's Strategy& practice estimates that pharmaceutical companies that fully industrialize AI use cases could add **$254 billion** in annual operating profit worldwide by 2030 (strategyand.pwc.com), but that value is only accessible to organizations that treat AI maturity as a deliberate, staged, and governed journey rather than a collection of disconnected pilots.

Introduction and Background

Artificial intelligence has moved from a peripheral research curiosity to a strategic priority across biotech and pharmaceutical organizations in the space of roughly five years. Advances in deep learning, exemplified by protein-structure prediction tools such as AlphaFold, alongside the proliferation of generative AI (Gen AI) platforms like ChatGPT and Claude, have convinced most life-sciences leadership teams that AI adoption is not optional. According to Define Ventures' survey of executives at 16 of the top 20 pharmaceutical companies,

70% of pharma leaders describe AI as an "immediate priority," a figure that rises to **85%** among the largest firms(fiercepharma.com). Roughly **80%** of respondents in that same survey said their companies are increasing AI budgets, while only **15%** are holding budgets flat (fiercepharma.com).

Enthusiasm, however, has consistently outrun operational discipline. A November 2024 survey of 100 senior life-sciences executives conducted by law firm Arnold & Porter, reported by Axios, found **75%** of respondents said their organizations began implementing AI within the past two years, and **86%** said they would deploy AI tools within two years or less (axios.com). About **80%** of companies use or plan to use AI in research and development (R&D), **62%** in manufacturing, and **45%** in marketing. Yet only **53%** of companies already using AI have established formal policies and standard operating procedures (SOPs), and just **51%** conduct regular audits of their AI systems (axios.com). This is the definition of an organization that has adopted AI faster than it has matured its capacity to govern it.

The consequences of this gap are not hypothetical. Industry analyses cited widely across the sector estimate that around **95%** of enterprise generative AI pilots fail to deliver measurable value, a figure that traces to MIT's Project NANDA research published in July 2025 (forbes.com). The Forbes analysis attributes most of these failures to misaligned tasks and poor organizational integration rather than to the underlying technology itself (forbes.com). In other words, the bottleneck is rarely the model. It is the surrounding organization: its data foundations, its governance structures, its validation discipline, and its change-management capacity.

This is precisely the gap that maturity models are designed to close. A maturity model provides a structured way to answer questions that most biotech executives cannot currently answer with confidence: Which AI use cases are governed and which are informal? What validation rigor does a given AI system require under Good Practice (GxP) rules? Is the organization's data infrastructure capable of supporting AI beyond isolated proofs of concept? Has accountability for AI outcomes been assigned to a specific governance body, or does it remain diffuse across IT, R&D, and quality functions?

This report defines and synthesizes a **biotech AI maturity model** by drawing on the published frameworks most directly applicable to life sciences: the ISPE's GAMP AI Maturity Model for GxP applications, which ties AI maturity to validation burden (ispe.org); Cradle.bio's five-level ML maturity ladder for biologics discovery, modeled on the automotive industry's SAE levels of autonomous driving and detailed further below; Axio BioPharma's Biomanufacturing AI Maturity Index (BAMI), which diagnoses why AI pilots stall before reaching governed, repeatable deployment in manufacturing environments (axiobiopharma.com); a four-stage enterprise adoption model inspired by Stanford's Professor Melissa Valentine and popularized for life sciences by Sakara Digital (sakaradigital.com); and a generative AI capabilities model for drug development co-authored by consultants at CGI and Roche and published through DIA's Global Forum (globalforum.diaglobal.org). It also incorporates guidance from KPMG's responsible AI adoption framework for life sciences (kpmg.com) and regulatory activity from the FDA and the European Union.

The Five-Stage Biotech AI Maturity Model

Synthesizing the published frameworks above yields a consolidated five-stage model applicable across biotech functions, from discovery biology to clinical development to manufacturing to commercial operations. Each stage is distinguished by three variables: the degree of organizational sanction (informal versus

governed), the degree of system autonomy (human-in-the-loop versus self-correcting), and the corresponding validation burden under GxP frameworks such as the ISPE's AI Maturity Model, which ties validation activity directly to a system's control design and autonomy (ispe.org).

Stage 1: Ad Hoc and Shadow AI Use

At the earliest stage, AI use is individual, informal, and largely invisible to central governance. In Sakara Digital's framing, this is "**Ad Hoc Use**: individual experimentation with little coordination" (sakaradigital.com). In Cradle.bio's ML maturity ladder for biologics, the equivalent starting point is "Level 0," in which no machine learning is used at all and teams rely on "traditional protein engineering that relies on semi-rational or rational approaches" (cradle.bio). Crucially, Stage 1 in a biotech context also encompasses what the industry now calls shadow AI: unsanctioned use of consumer-grade generative AI tools by individual employees.

The scale of Stage 1 activity is larger than most compliance functions assume. A BlackFog survey of 2,000 employees conducted by Sapio Research found that **49%** reported using AI tools not sanctioned by their employer at work (blackfog.com). An IBM-sponsored study of American office workers found that while **80%** use AI in their roles, only **22%** rely exclusively on employer-approved tools, and among Gen Z employees specifically, **35%** said they are likely to use only personal AI applications rather than company-approved ones, compared with **14%** of employees in other age groups (ibm.com). Fierce Healthcare, reporting on a Wolters Kluwer survey of more than 500 health professionals, found **40%** had encountered unauthorized AI tools at work and **17%** had used them personally (fiercehealthcare.com).

In GxP terms, Stage 1 corresponds to the ISPE model's lowest control-design tier, where "the system is used in parallel to the normal GxP processes" and has no direct influence on data integrity, product quality, or patient safety, meaning formal validation is not mandatory but human oversight of outputs remains essential (ispe.org). The risk at this stage is not the AI system's technical capability. It is the absence of any organizational record of what data has been exposed to third-party tools, a blind spot that KPMG describes as introducing "significant risks, including data privacy vulnerabilities, security gaps, compliance breaches" (kpmg.com).

Stage 2: Localized Pilots and Proofs of Concept

At Stage 2, AI moves from individual experimentation to team-level pilots with a defined scope, but without cross-functional coordination or enterprise governance. Sakara Digital labels this "**Localized Projects**: team-level pilots and MVPs [minimum viable products]" (sakaradigital.com). The DIA-published Gen AI capabilities model for drug development describes an analogous entry point, "**Basic AI-Powered Interaction**," defined as "simple, AI-driven Q&A and chatbot functions" requiring only "access to baseline generative AI services locally, online, or as a cloud service" (globalforum.diaglobal.org).

This is the stage at which most biotech organizations currently sit, and where most also stall. Deloitte's 2026 Life Sciences Outlook Survey of 280 C-suite biopharma and medtech executives found that only **22%** of life-sciences leaders have successfully scaled AI, and just **9%** report achieving significant returns on their investments (deloitte.com). ZS's 2026 CDIO research, based on a survey of 115 U.S.-based pharma and biotech technology executives conducted by The Harris Poll in July 2025, found that only about **40%** of AI

pilots make it to scaled deployment, and that nearly six in ten technology leaders pursue innovation only when the value story is already clear (zs.com). At the ML level, Cradle.bio's Level 1 ("Human Assessment") sits here: tools such as AlphaFold help scientists understand protein structure, but "decisions about what to design or test still rest entirely with humans" (cradle.bio).

Under the ISPE GAMP framework, Stage 2 pilots that begin to influence GxP decisions cross into "AI validation level III," requiring documented justification of model selection, training-data verification, model quality assurance after training, input-data monitoring, and defined retraining procedures (ispe.org). Organizations that skip this validation discipline while scaling a pilot's scope are the ones most likely to generate the 95% pilot-failure statistic cited above, because the failure surfaces only once the system encounters an edge case outside its original, narrowly validated scope.

Stage 3: Governed, Programmatic Adoption

Stage 3 marks the inflection point at which AI stops being a collection of disconnected pilots and becomes a governed program with defined accountability. Sakara Digital calls this "**Programmatic Use**: cross-functional deployment and governance" (sakaradigital.com). KPMG frames the mechanism as an "AI governance council," a cross-functional body that should "comprise cross-functional expertise from information technology, cybersecurity, legal, privacy, compliance, third-party risk, enterprise risk management, finance, supply chain, and internal audit" (kpmg.com).

As a point of reference, the FDA's CDER established a dedicated CDER AI Council in 2024 "to provide oversight, coordination, and consolidation of CDER activities around AI use" (fda.gov). Novartis provides a concrete corporate example: its published responsible-AI framework describes "a human-centered approach in using Artificial Intelligence to reimagine medicine," built around eight named principles including Accountability, Mitigate Bias, Respect Privacy, and Transparent and Explainable, applied across "over 100 use cases already developed" (novartis.com).

At Stage 3, GxP validation maturity typically sits at ISPE AI validation levels III to IV: systems operate with retraining discipline but with meaningful human control still in place, and organizations begin tracking model-quality key performance indicators (KPIs) in operation (ispe.org). Adoption data suggests this is where the industry's governance gap is widest: Define Ventures found that about **80%** of pharma leaders report their companies have already created a dedicated AI governance structure, with another **20%** in the process of setting one up (fiercepharma.com), yet Axios reports only **53%** of companies using AI have documented policies and SOPs and just **51%** conduct regular audits (axios.com). A governance structure that exists on paper without documented policy and audit cadence has not, in practice, reached Stage 3.

Stage 4: Enterprise Integration and Cross-Functional Scaling

At Stage 4, AI capabilities connect across previously siloed functions and phases, and the organization's data architecture is deliberately designed to support that connectivity. Sakara Digital's fourth stage, "**Enterprise Ecosystems**," describes "fully embedded agentic systems and strategic alignment" (sakaradigital.com). Cradle.bio's Level 3 ("ML Generation and Learning") captures the discovery-science equivalent: ML models

generate entirely new candidate molecules and "close the loop between ML systems and the wet lab," with organizations either building enterprise-grade ML platforms internally or adopting existing ones to support scalable discovery workflows (cradle.bio).

Bristol Myers Squibb (BMS) offers the clearest documented example of this stage in small-molecule discovery. As of 2025, all of BMS's "predict first"-enabled small-molecule programs use AI to evaluate properties like efficacy prior to synthesis, "a significant leap from just 5% in 2021," and the company applies a similar approach to nearly half of its large-molecule experiments (pharmavoice.com).

ZS's 2026 CDIO research quantifies the infrastructure investment this stage requires: pharma and biotech chief digital and information officers (CDIOs) report increasing investment in cloud and infrastructure (**88%**), data products and platforms (**86%**), and AI platforms specifically (**84%**) over the next twelve months (zs.com). Under the ISPE GAMP framework, Stage 4 systems typically sit at validation level IV, where update processes are partially automated and the organization must maintain a formal notification process for cases requiring retraining or falling outside the validated operating range (ispe.org).

Stage 5: Autonomous and Agentic Systems

The final stage involves AI systems that operate with minimal human coordination, correct their own parameters, and, in the most advanced form, take on agentic decision-making roles. Cradle.bio's top level, "AI Agents and Decision Making," is described as "akin to SAE Levels 4 and 5: largely autonomous operation within defined limits, with optional human oversight," in which software can "choose which programs to advance based on target product profiles, allocating experimental bandwidth, or refining assays" (cradle.bio). Notably, the authors of the parallel ISPE framework state plainly, in reference to its five control-design levels (a separate scale from its six AI validation levels), that "to our knowledge, there are currently no systems in pharmaceutical production at level 4 or 5" (ispe.org).

The DIA-published Gen AI model reaches a similar conclusion for drug development workflows, describing its top level as "**Self-Learning and Adaptive AI Systems**" capable of "multistep decision-making processes" and personalized recommendations in dynamic environments, but noting this requires "optimization of Gen AI models (task-specific) and model organization to perform tasks (agents)" that few organizations have built (globalforum.diaglobal.org). Under the ISPE GAMP validation framework, this stage corresponds to "AI validation level VI," for which the authors state candidly that "there is no validation concept available now to ensure regulatory compliance for systems in this category" (ispe.org).

Stage 5 is therefore best understood as an aspirational endpoint rather than a present operating reality for regulated biotech workflows. ZS's CDIO research shows agentic automation is moving from concept toward limited practice, with **45%** of pharma and biotech technology leaders planning agentic workflows in IT operations and **41%** planning them for R&D discovery, but even these leaders remain cautious in patient-facing functions, favoring smaller-scale automation with human-in-the-loop checks (zs.com).

Table 1 below summarizes the five stages and maps them to representative capabilities, GxP validation burden, and the governance mechanism each stage requires.

Stage	Organizational Sanction	Representative Capability	GxP Validation Burden	Governance Mechanism
1. Ad Hoc and Shadow AI	Informal, largely unsanctioned	Individual employees use consumer chatbots for drafting, summarization	None required (parallel to GxP process) but visibility gap is acute	None; ~49% of employees report unapproved use
2. Localized Pilots	Team-level, siloed	Single-use-case chatbots, AlphaFold-assisted structure review, narrow ML ranking models	AI validation level III begins to apply	Ad hoc project sponsor; no cross-functional oversight
3. Governed, Programmatic Adoption	Cross-functional, policy-backed	Multiple use cases under a documented AI policy and audit cadence	AI validation level III to IV	Formal AI governance council spanning IT, legal, compliance, risk (kpmg.com)
4. Enterprise Integration	Organization-wide, platform-based	Cross-phase active learning loops (e.g., BMS "predict first"), unified data platforms	AI validation level IV, with model-quality KPI monitoring	Enterprise AI platform team plus governance council; heavy infrastructure investment
5. Autonomous / Agentic Systems	Aspirational; minimal current deployment	Self-correcting agentic systems making programmatic decisions	AI validation level VI, no established validation concept yet (ispe.org)	Undefined; regulators and industry bodies are still developing control frameworks

The table underscores an important, honest finding: the overwhelming majority of biotech and pharma AI activity today sits in Stages 1 through 3, and the industry's most advanced documented examples reviewed here sit at Stage 4 (BMS) and Stage 3 governance (Novartis). No credible source reviewed for this report claims a production biotech system has reached full Stage 5 autonomy in a GxP-regulated workflow. Organizations that market themselves as operating at "Stage 5" maturity should be treated with skepticism until they can produce documented validation evidence consistent with ISPE's level VI criteria, which the framework's own authors acknowledge does not yet exist in a finalized form.

Implementation Considerations and Process Changes

Progressing through the maturity stages requires deliberate investment across five interlocking domains: governance structure, data infrastructure, validation discipline, talent, and regulatory alignment. Skipping any one of these typically explains why organizations stall at Stage 2, regardless of how sophisticated their underlying AI models are.

Governance structure. KPMG's guidance is unambiguous that an AI governance council is a leading practice, not an optional add-on, and that its mandate should extend beyond initial project approval into "post-implementation" review: "Strengthening postmortem reviews to confirm that AI projects or programs were developed in accordance with regulatory requirements and align with the approved business case is essential" (kpmg.com). Johnson & Johnson's Vice President of Global Audit and Assurance, Jessica Kahl-Winter, described this cross-functional model directly: "Very early, our company established rules of the road about

what we expect responsible use to look like... We also created a cross-functional group to oversee AI's development that made sure that everyone, data science, tech, legal, compliance, and our business leaders, had a seat at the table" (kpmg.com).

Data infrastructure. ZS's CDIO research found **68%** of pharma and biotech technology executives say neglecting data quality and governance early is the primary reason AI initiatives fail (zs.com). In biomanufacturing specifically, Axio BioPharma's BAMI framework identifies "data foundation and cross-system interoperability" as its first of five diagnostic dimensions, arguing that AI in biomanufacturing "keeps stalling at the pilot stage" because "the blocker is rarely the model. It is the operating environment around it: the data foundation, the governance, and the way sponsors and CDMOs [Contract Development and Manufacturing Organizations] coordinate" (axiobiopharma.com).

Validation discipline. The ISPE GAMP framework's core insight is that validation burden should scale with a system's autonomy and control design, not be applied uniformly. A locked-state ML system that requires manual retraining (validation level III) demands documented training-data verification and model quality assurance, while a self-triggered learning system with human oversight at every decision point (level IV) additionally requires "monitoring of model quality in operation" and "controlling quality KPIs and notification process" (ispe.org). Organizations that apply level VI rigor to a level II chatbot waste resources; organizations that apply level II rigor to a level IV clinical-decision tool put patients at risk.

Talent. Skills shortages are widely cited as a barrier to digital transformation and AI adoption, and some large organizations are responding with workforce-wide AI training programs. Moderna's parallel enterprise-wide generative AI rollout, discussed in the case studies below, illustrates a similarly aggressive workforce-proficiency posture.

Regulatory alignment. Progressing through the maturity stages must occur in step with, not ahead of, regulatory expectation. In January 2025, the FDA issued draft guidance on "Considerations for the Use of Artificial Intelligence to Support Regulatory Decision Making for Drug and Biological Products," informed by feedback from a December 2022 Duke Margolis Institute expert workshop, more than 800 public comments on a May 2023 discussion paper, and CDER's own experience reviewing over **500** AI-component submissions between 2016 and 2023 (fda.gov). In January 2026, CDER and the Center for Biologics Evaluation and Research (CBER) collaborated with the European Medicines Agency to publish 10 joint guiding principles for good AI practice in drug development (fda.gov).

On the European side, the EU AI Act imposes a staged compliance timeline after entry into force: **6** months for prohibited AI systems, **12** months for general-purpose AI (artificialintelligenceact.eu), and, as postponed by Regulation (EU) 2026/1744 (eur-lex.europa.eu), **2 December 2027** for high-risk AI systems under Annex III and **2 August 2028** for high-risk systems under Annex I, which includes medical devices. Providers of high-risk AI systems must "establish a risk management system throughout the high risk AI system's lifecycle," conduct data governance to ensure training data is "relevant, sufficiently representative and, to the best extent possible, free of errors," and design systems to "allow deployers to implement human oversight" (artificialintelligenceact.eu). KPMG notes that ISO 42001, an international standard for AI management systems, "can help organizations meet many of the requirements of the EU AI Act," though it "may not directly address all specific provisions of the legislation" and often needs supplementing with targeted risk assessments (kpmg.com).

Organizations may seek outside support to translate AI governance frameworks into operational reality without displacing existing compliance infrastructure. The maturity progression described in this report applies regardless of which specific vendors, cloud providers, or foundation models a given organization selects.

Data Analysis and Evidence

The quantitative picture across independent surveys is remarkably consistent: strong strategic intent, weak governance follow-through, and a wide gap between pilot activity and scaled, measurable value.

On strategic intent, Define Ventures' survey of 16 of the top 20 pharmaceutical companies found **70%** of leaders call AI an "immediate priority" (**85%** among the largest firms), and "a reduction in administrative burden equating to 'success' in AI for **100%** of the leaders surveyed" reflects how narrowly value has so far been defined (fiercepharma.com). PwC's Strategy& practice, analyzing more than 200 AI use cases with 25 industry and technology experts, found AI use cases in operations account for **39%** of the total potential impact by boosting production, material, and supply-chain efficiency, R&D accounts for **26%**, commercial for **24%**, and enabling functions such as IT, finance, and legal for **11%** (strategyand.pwc.com). In aggregate, PwC projects pharmaceutical companies could gain an additional **$254 billion** in annual operating profits worldwide by 2030 if they fully industrialize AI use cases, an estimate built on a 5.7% compound annual growth rate (CAGR) baseline for the industry absent AI effects, broken down as **$155 billion** in the United States, **$52 billion** in emerging markets, **$33 billion** in Europe, and **$14 billion** in the rest of the world (strategyand.pwc.com).

On governance follow-through, the picture is thinner. Axios reported that only **53%** of life-sciences companies already using AI have formal policies and SOPs, and just **51%** conduct regular audits (axios.com). KPMG's 2024 CEO Outlook survey separately found "a striking 64 percent of life sciences executives now prioritize AI investments" (kpmg.com), a strategic prioritization figure that dwarfs the governance-maturity figures above it. Deloitte's 2026 survey of 280 C-suite biopharma and medtech executives, conducted from August to September 2025, found **78%** expect AI to play a central role in driving major change, and **29%** of biopharma leaders and **31%** of medtech leaders plan to use AI tools or training specifically to improve workforce productivity, yet only **14%** report full implementation of AI in daily workflows, with another **40%** still working toward that goal (deloitte.com).

Table 2 below compares the five published maturity frameworks synthesized into this report's model, showing how each source characterizes the entry and exit points of AI maturity in its respective domain.

Framework	Publisher	Domain Focus	Number of Stages	Entry-Level Description	Top-Level Description
GAMP AI Maturity Model	ISPE D/A/CH Working Group	GxP validation across pharma	5 control-design stages, 6 AI validation levels	System runs parallel to GxP process, no influence on quality (ispe.org)	Self-learning, self-correcting system; "no validation concept available now" (ispe.org)
ML Maturity Ladder	Cradle.bio	Biologics discovery R&D	5 levels (0 to 4)	No machine learning used; traditional protein engineering (see Stage 1 above)	AI agents making autonomous programmatic decisions (cradle.bio)

Framework	Publisher	Domain Focus	Number of Stages	Entry-Level Description	Top-Level Description
BAMI	Axio BioPharma	Biomanufacturing operations	5 diagnostic dimensions	Isolated pilots with no cross-system interoperability (axiobiopharma.com)	Governed, repeatable, scalable operational deployment (axiobiopharma.com)
Stanford / Sakara model	Sakara Digital, citing Prof. Melissa Valentine	Enterprise-wide adoption	4 stages	Individual experimentation with little coordination (sakaradigital.com)	Fully embedded agentic systems and strategic alignment (sakaradigital.com)
Gen AI Capabilities Model	CGI and Roche authors, DIA Global Forum	Drug development workflows	4 levels	Basic AI-powered Q&A and chatbot interaction (globalforum.diaglobal.org)	Self-learning and adaptive AI systems (globalforum.diaglobal.org)

Two patterns emerge from this comparison. First, the frameworks that define stages or levels converge on roughly four to six (BAMI is organized as five diagnostic dimensions rather than stages), and each anchors its entry point in informal, human-controlled use and its exit point in autonomous, self-correcting systems, a convergence that lends credibility to the five-stage synthesis presented in this report. Second, the ISPE authors state that there are currently no systems in pharmaceutical production at control-design level 4 or 5, and this report found no documented example of a production Stage 5 system in any of the frameworks reviewed. The DIA-published model cites RAND Corporation research on why AI projects fail, noting that root causes center on "misunderstanding or miscommunicating the problem to be solved, prioritizing cutting-edge technology over solving real user problems, lacking the necessary infrastructure to manage and deploy models, and attempting to apply AI to problems beyond its capabilities" (globalforum.diaglobal.org), a reminder that maturity progression is fundamentally an organizational discipline problem, not primarily a model-capability problem.

Case Studies and Real-World Examples

Moderna: Enterprise-Wide Generative AI Adoption

Moderna's collaboration with OpenAI represents the most extensively documented Stage 3-to-4 transition in biotech. Rather than approving generative AI use case by case, Moderna's leadership set an explicit organizational goal: "achieve 100% adoption and proficiency of generative AI by all its people with access to digital solutions in six months" (openai.com). The company built an internal chatbot, mChat, at the beginning of 2023 on OpenAI's API, which was "adopted by more than 80% of employees across the company," establishing a foundation before the subsequent rollout of ChatGPT Enterprise (openai.com). Within two months of the ChatGPT Enterprise rollout, employees had built **750** custom GPTs across the company for department-specific tasks (openai.com). By the time of reporting, Moderna's legal department had reached **100%** adoption of ChatGPT Enterprise, with Chief Legal Officer Shannon Klinger noting it "lets us focus our time and attention on those matters that are truly driving an impact for patients" (openai.com). This case

illustrates a Stage 3 characteristic directly: cross-functional deployment paired with an internal governance and change-management program, including an internal forum on AI that grew to **2,000** active weekly participants (openai.com).

Insilico Medicine: An AI-Discovered Drug Reaches Phase III

Insilico Medicine's rentosertib program illustrates Stage 4 maturity within drug discovery specifically. Rentosertib, an oral small-molecule inhibitor targeting TNIK (TRAF2- and NCK-interacting kinase) for idiopathic pulmonary fibrosis (IPF), was discovered and designed through Insilico's Pharma.AI platform and was announced as initiating its Phase III clinical trial in July 2026 (clinicalresearchnewsonline.com). Chief Executive Officer Alex Zhavoronkov described the program's development speed as a company record: "Usually AI helps you significantly to accelerate preclinical R&D to go from zero to developmental candidate. Our records are 9-18 months to go from zero to this developmental candidate" (clinicalresearchnewsonline.com). The Phase III trial itself, however, is described by Insilico's Vice President of Clinical Development, Carol Satler, in traditional terms: a "randomized, double-blind, placebo-controlled parallel group study" enrolling **320** patients over 52 weeks (clinicalresearchnewsonline.com), with a projected New Drug Application (NDA) submission by March 2030 and potential approval by September 2030 (clinicalresearchnewsonline.com). This case is instructive precisely because it shows AI maturity is not uniform across a single program: Insilico's discovery-stage AI use sits closer to Stage 4, while the downstream clinical validation process remains almost entirely governed by conventional, human-controlled regulatory science, exactly as the ISPE framework would predict for a GxP-critical decision point.

Bristol Myers Squibb: "Predict First" Across the Discovery Portfolio

Bristol Myers Squibb has institutionalized what the company describes as a "predict first" strategy that fundamentally changes how it approaches drug discovery. As of 2025, all of BMS's "predict first"-enabled small-molecule programs use AI to evaluate properties like efficacy prior to synthesis, "a significant leap from just 5% in 2021," and the company is applying a similar approach to nearly half of its large-molecule experiments (pharmavoice.com). Mike Ellis, BMS's Senior Vice President and head of Discovery and Development Sciences, summarized the cultural shift bluntly: "We don't go into the lab and make things unless we have a good idea of what the forecast looks like" (pharmavoice.com). Among the company's "predict first" programs is an effort to find CELMoD (cereblon E3 ligase modulator) agents for sickle cell disease, where Ellis said the team hit a "plateau" as it worked toward identifying a clinical candidate before bringing in more computational scientists and crossing the months-long plateau within weeks (pharmavoice.com).

Novartis: A Documented Enterprise Responsible-AI Framework

Novartis provides one of the most publicly detailed examples of Stage 3 governance infrastructure in the industry. Its published framework, titled "Novartis' commitment to the ethical and responsible use of Artificial Intelligence Systems," describes "a human-centered approach in using Artificial Intelligence to reimagine medicine" (novartis.com), organized around eight named themes: Empower Humanity, Accountability, Mitigate

Bias, Respect Privacy, Transparent and Explainable, Safe and Secure, Environmental Sustainability, and Review, Learn and Adapt. The company reports having "applied AI broadly across Novartis," with "over 100 use cases already developed" spanning R&D, business operations, and patient and healthcare-community engagement (novartis.com). This case is notable for what it demonstrates about maturity as an evolving state rather than a fixed achievement: Novartis frames its own initiative not as a completed transformation but as an ongoing digital transformation "since 2018," suggesting even large, well-resourced pharmaceutical companies treat AI governance maturity as a multi-year, continuously revisited program rather than a project with a defined end date (novartis.com).

A Mid-Size Biotech Navigating Stage 2 to Stage 3 (Hypothetical Example)

To illustrate how the maturity model applies practically to an organization without the resources of a top-20 pharmaceutical company, consider a hypothetical 400-employee clinical-stage biotech (Hypothetical Example) with two Phase II oncology programs. Its research scientists have been individually using consumer generative AI tools to summarize literature (Stage 1), and its clinical operations team has piloted a single AI-assisted trial-monitoring dashboard without formal validation documentation (Stage 2). Following ZS's finding that neglected data governance is the leading cause of AI initiative failure (zs.com), such an organization's most defensible next step is not acquiring more sophisticated AI models, but standing up a lightweight cross-functional governance body, modeled on KPMG's guidance (kpmg.com), that formally inventories existing AI use (including shadow use), documents which systems influence GxP decisions under the ISPE validation-level framework, and establishes an approved-tools list before scaling any single pilot further. This hypothetical sequencing mirrors the documented Novartis and Moderna trajectories: governance infrastructure preceded, rather than followed, enterprise-wide scaling in both real-world cases.

Implications and Future Directions

Several structural trends are likely to reshape how biotech organizations navigate this maturity model over the next several years. First, regulatory deadlines are converging with the industry's own adoption curve rather than trailing it, as they historically have with earlier waves of digital transformation. The EU AI Act's staged timeline, culminating, as postponed by Regulation (EU) 2026/1744, in an application date of **2 August 2028** for high-risk systems under Annex I (eur-lex.europa.eu), and the FDA's growing submission volume, with CDER having reviewed over **500** AI-component submissions from 2016 to 2023 alone (fda.gov), mean organizations that remain at Stage 1 or Stage 2 by the time these deadlines arrive will face compliance exposure that compounds their existing competitive disadvantage.

Second, agentic AI is likely to be the primary battleground for Stage 4-to-5 progression over the coming three to five years, but the evidence gathered in this report suggests the industry will approach it cautiously in regulated workflows specifically. ZS's research shows pharma and biotech leaders are already comfortable piloting agentic workflows in low-risk domains such as IT operations (**45%** planning adoption) while remaining deliberately conservative in patient-facing and GxP-critical functions (zs.com). This bifurcation, aggressive

automation in back-office and enabling functions, cautious human-in-the-loop deployment in clinical and manufacturing contexts, is likely to persist and may become a durable structural feature of biotech AI maturity rather than a temporary transition state.

Third, the shadow AI problem documented throughout this report is unlikely to resolve through prohibition alone. KPMG's observation that shadow AI persists because employees seek "quick solutions or innovation, bypassing standardized policies and procedures" (kpmg.com), suggests that organizations progressing to Stage 3 governance must pair policy enforcement with genuinely usable, approved alternatives. A ban without a viable substitute simply pushes usage further underground and further degrades the organization's already limited visibility into its own AI risk surface.

Fourth, the data infrastructure investments organizations are making now, cited by ZS at **88%** for cloud and infrastructure, **86%** for data products and platforms, and **84%** for AI platforms specifically (zs.com), will determine which organizations are structurally capable of reaching Stage 4 within the next five years and which remain permanently capped at Stage 2 or 3 regardless of their AI model sophistication. Given that the ZS survey found only **17%** of respondents can currently prove measurable value from data, digital, and AI investments in R&D discovery today, though **42%** expect to within a year (zs.com), the sector appears to be at an inflection point where the returns on multi-year infrastructure investment are only now beginning to materialize.

Frequently Asked Questions (FAQs)

What is a biotech AI maturity model? A biotech AI maturity model is a staged framework describing how an organization's AI capability progresses from informal, individual use toward governed, enterprise-integrated, and eventually autonomous systems. This report synthesizes five such stages from published frameworks including the ISPE's GAMP AI Maturity Model (ispe.org) and Cradle.bio's ML maturity ladder for biologics discovery, both discussed in detail above.

How widespread is AI adoption in biotech today? Very high in intent, much lower in execution. Roughly **75%** of life-sciences executives report beginning AI implementation within the past two years, and **86%** plan further deployment within two years (axios.com), yet Deloitte found only **22%** of life-sciences leaders have actually scaled AI successfully (deloitte.com).

What is a life sciences AI maturity framework used for? It is used to diagnose an organization's current governance, data, and validation posture against a structured benchmark, allowing leadership to identify specific gaps (for example, missing audit cadence or undocumented validation) rather than relying on vague self-assessment. KPMG recommends beginning with "a comprehensive inventory of internally developed and third-party AI applications, including 'shadow AI' applications" as the diagnostic starting point (kpmg.com).

What is shadow AI in life sciences, and why does it matter? Shadow AI is the unsanctioned, ungoverned use of AI tools, typically consumer-grade chatbots, by employees outside official IT and compliance channels (kpmg.com). It matters in biotech specifically because of the presence of protected health information, clinical trial data, and pre-competitive molecular intellectual property, any of which could be exposed through an unmonitored chatbot session. A BlackFog survey of 2,000 employees found that **49%** reported using AI tools not sanctioned by their employer at work (blackfog.com).

What is AI governance for biotech companies, concretely? It typically means establishing a cross-functional AI governance council spanning IT, legal, compliance, privacy, and risk management (kpmg.com), documenting AI policies and SOPs, conducting regular audits, and maintaining a validation approach scaled to each system's autonomy under frameworks such as ISPE's GAMP model (ispe.org).

What compliance considerations apply to generative AI in drug discovery? Generative AI systems that influence GxP decisions fall under validation frameworks requiring documented model selection rationale, training-data verification, and ongoing model-quality monitoring (ispe.org). In the EU, whether a system is high-risk under the AI Act depends on whether it is classified as high-risk pursuant to Article 6(2) and Annex III or Article 6(1) and Annex I (eur-lex.europa.eu); for systems that are, the Act requires risk management systems and human oversight design (artificialintelligenceact.eu). In the US, the FDA has published draft guidance (2025) with recommendations on the use of AI to produce information or data intended to support regulatory decision-making for drugs, and, with the EMA, 10 guiding principles (January 2026) (fda.gov).

How should a biotech company begin implementing an AI maturity program? Start with an honest inventory of existing AI use, including shadow use, map each use case against a validation-burden framework like ISPE's, and stand up cross-functional governance before scaling any pilot further. ZS's research is direct on this point: **68%** of pharma and biotech technology executives cite neglected data quality and governance as the leading cause of AI initiative failure (zs.com), meaning governance and data foundations should precede, not follow, technical scaling.

What is a pharma AI maturity model, and how does it differ from a biotech AI maturity model? The terms are largely interchangeable in practice; "pharma AI maturity model" typically emphasizes large, commercial-stage organizations with established manufacturing and marketed-product operations, while "biotech AI maturity model" more often applies to earlier-stage, R&D-intensive organizations. The underlying stages, governance, data, validation, talent, and regulatory alignment, apply identically across both, as reflected in this report's synthesis drawing on frameworks originating in both large pharma and specialized biotech (Cradle.bio, Insilico Medicine) contexts.

Conclusion

The evidence assembled in this report points to a consistent conclusion: biotech and pharmaceutical organizations are not short on AI ambition, and increasingly not short on AI capability either. What most remain short on is structured maturity, the governance councils, documented validation levels, data infrastructure, and trained workforce that convert isolated pilots into dependable, auditable, enterprise-scale capability. The gap between the **70%** to **86%** of executives reporting active AI adoption plans and the roughly **22%** who report having actually scaled AI successfully is not a technology gap. It is an organizational maturity gap, and it is closeable through deliberate, staged investment rather than through acquiring more sophisticated models.

The five-stage model synthesized here, ad hoc and shadow use, localized pilots, governed programmatic adoption, enterprise integration, and autonomous or agentic systems, gives biotech leaders a shared vocabulary for locating their organization honestly on this curve. The evidence from Moderna, Insilico Medicine, Bristol Myers Squibb, and Novartis demonstrates that Stage 3 and Stage 4 maturity are achievable

within a few years of committed investment, but also that Stage 5 remains, by the acknowledgment of the very frameworks proposing it, an aspiration rather than a documented production reality anywhere in regulated biotech today.

Regulatory timelines from the FDA and the EU AI Act are converging with this maturity curve rather than trailing behind it, which means the cost of remaining at Stage 1 or Stage 2 is rising, not falling. Organizations that treat AI maturity as a genuine, multi-year organizational transformation, rather than a procurement decision or a communications talking point, are the ones best positioned to capture the estimated **$254 billion** in additional annual operating profit that full industrialization of AI could unlock across the pharmaceutical industry by 2030. The path from shadow AI to governed, enterprise-scale capability is well documented by the organizations that have already walked it. What remains is the discipline to follow it deliberately, stage by stage, rather than skip ahead.

Source links

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