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Pharma AI Validation Packages for FDA & EMA Compliance

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Executive Summary

The pharmaceutical industry is rapidly integrating artificial intelligence (AI) across drug discovery, development, clinical trials, manufacturing, and quality processes. Recognizing the “transformative potential” of AI to accelerate medical innovation while ensuring safety, regulators have begun to issue detailed guidance on validating AI tools. In January 2025, the FDA released its first draft guidance on AI in drug and biologic development, outlining a **risk-based credibility assessment framework** for AI models used in regulatory applications (www.fda.gov). Similarly, in 2024–2026 the European Medicines Agency (EMA) issued a public **reflection paper** (September 2024) and, jointly with the FDA, **ten ‘good AI practice’ principles** (January 2026) that span the entire drug lifecycle (www.ema.europa.eu) (www.techscience.com). These documents reinforce that existing regulatory requirements (cGMP, GxP, data integrity) apply fully to AI/ML systems, while adding AI-specific elements such as **pre-specified context of use (COU)**, data provenance, transparency, bias control, and traceable documentation.

Sponsors should tailor **validation evidence packages** to the AI model’s context of use and risk. FDA’s nonbinding draft makes the timing and location of a credibility assessment plan’s submission depend on the model, its context of use and the sponsor’s engagement with FDA (FDA draft guidance). EMA places responsibility for fitness for purpose on the sponsor, applicant or holder, or manufacturer, as appropriate (EMA reflection paper). Assess applicable electronic-record and GxP obligations for each use; FDA’s Part 11 guidance recommends record-specific decisions based on predicate rules. Supporting assurance methods may include GAMP5-style validation. For high-risk applications, regulators may demand **detailed software documentation** – e.g. algorithm specifications, training logs, and datasets – alongside classical study reports (pmc.ncbi.nlm.nih.gov) (artificialintelligenceact.eu).

This report examines the evolving regulatory landscape and the components of AI validation packages in depth. We review FDA and EMA guidance, relevant international standards (e.g. IMDRF GMLP, GAMP5), and current practices in industry. We highlight differences and commonalities between U.S. and EU requirements, discuss case examples (e.g. AI-assisted trial design and real-world evidence in recent submissions), and present data on AI adoption in pharma. Finally, we analyze the implications for pharma companies: the need for robust data governance, software assurance, and multidisciplinary documentation. By integrating experts' perspectives and published research, this report provides a **comprehensive roadmap** for assembling documentary proof of AI validation that satisfies both FDA and EMA expectations.

Introduction and Background

Artificial intelligence (AI) – broadly defined as machine-based systems that make or influence decisions – is increasingly applied throughout the pharmaceutical product lifecycle (pmc.ncbi.nlm.nih.gov). In drug discovery, AI models identify promising compounds from chemical libraries or design novel candidates. In preclinical and clinical development, AI aids patient stratification, adaptive trial design, imaging analysis, and safety signal detection. Manufacturing and quality control benefit from predictive maintenance, anomaly detection, and process optimization. For example, AI/ML models have been used to predict patient outcomes, elucidate disease progression markers, and analyze large real-world datasets (www.fda.gov). The growing market reflects this trend – PwC reports that pharmaceutical AI investment is projected to jump from about $2 billion in 2025 to over $16 billion by 2034, and roughly 70% of pharma executives expect AI to "fundamentally reshape" operations within three years (www.pwc.com).

Despite the promise, AI's unique nature raises regulatory and compliance challenges. Traditional validation of software in pharma focuses on deterministic, validated functions. AI systems are data-driven, often complex or opaque ("black boxes"), and may evolve over time (especially if continuously learning). Regulators have long held that responsibility for safety and efficacy rests with the sponsor, not the tool. Accordingly, both the FDA and EMA emphasize that **AI does not create new authority to bypass existing rules** – instead, it must fit within the established framework for drugs, biologics, and medical devices (www.linkedin.com) (www.techscience.com). In practice, this means that all current regulations (GxP, electronic records, quality systems, etc.) fully apply to AI/ML tools in pharma. At the same time, regulators are collaborating with industry to clarify what specific evidence is needed to "trust" AI outputs in regulated submissions.

Historical Context of Regulation and AI in Pharma

The regulatory journey for software in pharmaceuticals has evolved over decades. In the U.S., 21 CFR Part 11 (Electronic Records; Electronic Signatures, 1997) established requirements for computerized systems; similarly, EU GMP Annex 11 (revised 2011) laid out controls for computer systems in manufacturing. These rules were historically applied to conventional computer processes (e.g. chromatography data systems, automated dispensing equipment). The rise of AI brings new issues of *algorithmic performance*, *training data integrity*, and *model validation*, which were not contemplated in older guidance.

In recent years, both FDA and EMA (along with other regulators) have signaled a shift. A series of public–private workshops and discussion papers (FDA's AI workshop reports, trans-Atlantic consortia) highlighted the need for updated guidance. Key milestones include FDA's "AI/ML Action Plan" (2021–23), the IMDRF

consensus on Good Machine Learning Practices (GMLP, 2021/25), and EMA's Big Data initiatives. These efforts reconfirm the fundamental principle that regulators care about **scientific validity and data integrity**, regardless of whether an insight is generated by humans or an algorithm (pmc.ncbi.nlm.nih.gov) (www.techscience.com). In practice, they are promoting a *risk-based approach*: the higher the impact on patient safety or product quality, the more rigorous the validation and documentation required.

Accordingly, in 2023–2026 both FDA and EMA have begun issuing formal documents that integrate AI considerations into pharma regulation. We summarize these:

- **FDA (USA):** In January 2025 the FDA released draft guidance **"Considerations for the Use of Artificial Intelligence To Support Regulatory Decision-Making for Drug and Biological Products"** (www.fda.gov). This is FDA's first guidance specifically on AI in the drug context (distinct from AI in devices). The nonbinding draft recommends defining the AI model's *context of use* (COU) as part of a risk-based credibility assessment (FDA draft guidance) (www.fda.gov) (www.linkedin.com). The guidance was informed by industry workshops and notes that FDA has reviewed **"more than 500 drug and biologic submissions with AI components since 2016"** (www.fda.gov). The draft guidance is open for comment and will eventually be finalized. Importantly, FDA emphasizes that AI guidance *enhances* – not replaces – existing regulations. FDA's final February 2026 CSA guidance concerns software used in medical-device production or quality management systems under 21 CFR Part 820. Using its methods by analogy in drug development does not establish that device requirements apply; Part 11 requires a separate scope assessment.
- **EMA (EU):** In July 2023 EMA published a **draft reflection paper on AI in the medicinal product lifecycle**, and finalized it as a guideline in September 2024 (www.ema.europa.eu). This paper articulates GDPR-style principles applied to AI: transparency, robustness, human oversight, and because pharmaceutical products are high-stakes, adherence to existing GxP standards. The EMA reflection explicitly states that *all existing EU pharma rules apply in full to AI/ML applications*, and urges sponsors to apply quality risk management to data and algorithms (www.linkedin.com) (www.techscience.com). On January 14, 2026, EMA and FDA jointly published **"Principles of Good AI Practice in Drug Development"**, identifying ten high-level principles guiding AI across the drug lifecycle (www.ema.europa.eu). These principles are broad (emphasizing evidence generation, monitoring, and human accountability) and intended to underlie future binding guidance. They also reflect ongoing EU legislation: the EU's proposed Biotech Act and new Pharmaceutical Legislation explicitly encourage AI innovation under strict controls (www.ema.europa.eu), and the EU AI Act entered into force on 1 August 2024 and became generally applicable on 2 August 2026, with exceptions. The Commission lists later high-risk transition dates of 2 December 2027 for Annex III uses and 2 August 2028 for systems embedded in regulated products; assess the applicable scope and duties as discussed below.
- **International Standards and ICH:** Globally, two major trends converge. First, the **IMDRF Good Machine Learning Practice (GMLP)** document (2021, with new versions around 2025 (www.fda.gov)) provides non-binding best practices for medical AI, focusing on reproducibility and safety. Second, **ICH** guidance has advanced: Q9(R1) (Quality Risk Management) is final FDA guidance. In the EU, E6(R3) (Good Clinical Practice) Principles and Annex 1 have been effective since 23 July 2025; Annex 2 was

adopted by ICH and CHMP in June 2026 and becomes effective on 15 January 2027. GAMP5 (Good Automated Manufacturing Practice, ISPE) was updated in 2022 and explicitly accommodates AI under rigorous validation and governance frameworks (www.techscience.com). In all cases, regulators emphasize *risk-based validation and traceability* rather than blanket bans on AI.

- **Other Regulators:** The EMA's stance is mirrored by other agencies. Japan's PMDA and Canada's Health Canada are similarly exploring AI guidance. A notable U.S. action was FDA's first **AI-assisted review pilot** completed in May 2025, and an Executive Order in 2025 mandating AI guidance review (outside the scope here but indicative of priority) (pmc.ncbi.nlm.nih.gov). Meanwhile, industry groups (e.g. Critical Path Institute, TransCelerate) are forming foundations to study AI validation and harmonize standards globally (pmc.ncbi.nlm.nih.gov).

In summary, the regulatory environment is in active flux. FDA and EMA explicitly tie future AI policy to existing frameworks: **FDA officials note that "AI credibility" must be established within the context of use, consistent with Part 11 and GxP requirements (www.techscience.com) (pmc.ncbi.nlm.nih.gov).** EMA reiterates that its statutes for drug safety/quality apply fully, and that AI tools must be governed by the same principles of validation, documentation, and human accountability (www.techscience.com) (www.ema.europa.eu).

The remainder of this report analyzes *how* sponsors can meet these expectations. We review the components of an "AI Validation Evidence Package" – the collection of documentation needed to prove compliance – for both FDA and EMA submissions. We draw on regulatory texts, comparison of guidance, technical literature, and expert commentary to outline best practices. Our aim is to provide a **comprehensive, evidence-based guide** to what documentary proof regulators will likely require for AI in pharmaceutical applications.

Regulatory Frameworks and Guidance

FDA (USA)

2025 Draft Guidance and Credibility Framework

On January 6, 2025, the FDA released a draft guidance titled *"Considerations for the Use of Artificial Intelligence To Support Regulatory Decision-Making for Drug and Biological Products"* (www.fda.gov). This draft guidance proposes a **risk-based credibility assessment framework** for AI models in a particular context of use; it is not for implementation and contains nonbinding recommendations (FDA draft guidance). The term *"credibility"* refers to the trustworthiness of an AI model's output for a specific **context of use** (COU) – i.e., the intended application such as dose prediction or trial endpoint analysis.

The guidance (non-binding draft) recommends sponsors to *pre-specify* the model's COU, including inputs, outputs, boundaries, and assumptions, *before* applying the model. It then advises a tiered, risk-based set of *credibility activities* based on the potential impact on decision-making. High-impact use (e.g. primary endpoint adjudication) demands the most rigorous validation and documentation; low-impact (e.g. scheduling or logistics) requires lighter oversight. This approach is consistent with FDA's recent shift in computer software oversight: focus on things that matter for patient safety and product quality (www.techscience.com).

Key points from the draft FDA guidance include **documentation** of: the model's development, training and test data provenance, performance benchmarks, potential biases and limitations, and post-market monitoring (if applicable). For electronic records, assess the applicable predicate-rule retention or submission requirements and whether electronic records are relied on for regulated activities. FDA recommends documenting whether specific records fall under Part 11; patient-record origin alone does not establish applicability. Select validation and audit-trail controls using the applicable requirements and a documented risk assessment. FDA encourages early communication (through pre-IND and mid-review meetings) to discuss AI approaches and evidence plans.

Although only a draft (final release pending review of public comments), FDA officials emphasize that this framework formalizes practices already seen in submissions. Commissioner Califf noted that FDA had already reviewed hundreds of AI-enabled applications since 2016 (www.fda.gov). FDA's CDER Center for Clinical Trial Innovation (C3TI) supports innovative clinical trial approaches. For now, sponsors can glean from the draft that FDA expects: **1) Pre-specified model plan and performance benchmarks; 2) Evidence of model validity across its intended domain; 3) Compliance with all relevant quality and electronic-record regulations.**

Other FDA Initiatives

In parallel, the FDA has released several related AI documents:

- **AI/ML Action Plan (2021–23):** Outlined steps for adaptive AI in devices, leading to current draft.
- **FDA's Good Machine Learning Practice (GMLP):** While originally conceived for devices, the IMDRF GMLP principles (adopted by FDA/IMDRF in 2021/2025) cover general best practices for AI in healthcare (e.g. dataset quality, monitoring) (www.fda.gov). These are not binding, but FDA staff often cite them as benchmarks for thorough design and validation.
- **Computer Software Assurance (CSA):** FDA's final February 2026 guidance recommends a risk-based assurance approach for software in medical-device production or quality management systems. Its methods may inform a voluntary assurance approach in a drug context, but the guidance does not make device rules applicable to all pharmaceutical software.
- **Software as a Medical Device (SaMD) Guidance:** If an AI tool in pharma qualifies as a medical device (e.g. a diagnostic algorithm), FDA's SaMD framework would also apply. This includes the IMDRF framework for SaMD, which emphasizes clinical association and careful risk categorization.
- **Regulatory Workshops:** FDA's Duke-Margolis workshop (Dec. 2022) and others provided industry input on what guidance should cover. The January 2025 draft acknowledges ~800 public comments on prior discussion papers in 2023 (www.fda.gov), showing active engagement.

In summary, FDA's stance is **"all existing rules still apply, plus new AI credibility criteria"**. Sponsors should treat an AI model almost like a novel device: define the intended use (COU), verify performance, document everything to the same standard as any other regulated component, and engage FDA early with evidence plans.

EMA (European Union)

September 2024 Reflection Paper

On September 30, 2024, the EMA finalized its **Reflection Paper on the use of Artificial Intelligence in the medicinal product lifecycle** (www.ema.europa.eu). This document, open for public consultation before adoption, sets out EMA's current thinking on AI in drug development and regulation. It covers human and veterinary medicines and spans *all stages* from discovery to post-authorization surveillance (www.ema.europa.eu).

Key themes in the EMA Reflection are:

- **Existing Frameworks Remain Primary:** The Reflection explicitly states that current EU pharmaceutical legislation (Directives and Regulations), EMA and national guidelines, and GxP rules apply in full to AI/ML applications. AI isn't carving out a new regulatory silo; rather, it must be integrated into existing processes (www.linkedin.com) (www.ema.europa.eu).
- **Principles of AI Use:** The paper highlights principles like safety, effectiveness, quality, transparency, ethical use, and human oversight. For instance, it notes regulators' "excitement" but also their need to address "regulatory challenges" from the evolving AI ecosystem (www.ema.europa.eu). The Reflection encourages discussions between developers and regulators (CHMP, National Agencies) early in development.
- **Documentation and Data:** While not prescriptive, EMA discusses the importance of data quality and traceability. It expects sponsors to apply quality risk management (ICH Q9) to datasets and algorithms. For example, Section 4 suggests describing training data sources, curation, and known limitations. Similarly, any algorithm changes (e.g. version updates) must be documented and validated.
- **Transparency:** There is emphasis on explainability to the extent feasible. AI outputs impacting labeling or safety decisions should be documented in a clear way. For example, if an AI identifies a patient subgroup at risk, the analysis and rationale should appear in the submission.
- **Alignment with Global Standards:** The Reflection notes coordination with international guidelines (e.g. IMDRF). It encourages using tools like Data Anonymization for training data (to comply with GDPR) and advocates post-market surveillance of AI.

Importantly, the EMA Reflection remains *non-binding*. It lays groundwork for future guidance but itself is advisory. However, sponsors should take it seriously. The reflection paper has the weight of EMA policy intent (as seen by its publication on the EMA site) (www.ema.europa.eu), and it serves as the basis for anticipated formal guidelines on AI. Notably, the EMA workplan (2022–2025) includes development of AI-specific guidances, and EMA staff have indicated that an official GxP guideline for AI is forthcoming.

FDA-EMA Joint Principles (Jan 2026)

The FDA and EMA issued a joint press release on January 14, 2026 announcing **"Guiding Principles of Good AI Practice in Drug Development"** (www.ema.europa.eu). This was the first formal EU–US co-publication addressing AI, comprising ten broad principles. While not legally binding, these principles

underscore the shared regulatory perspective:

- They cover **all phases** of the medicine lifecycle, from early research through manufacturing and post-market monitoring (www.ema.europa.eu). For example, principle highlights include responsible use of real-world data/AI for evidence generation, clear human accountability, and flexible lifecycle management of AI systems.
- The principles are targeted to all stakeholders in drug development: drug developers, applicants, marketing authorization holders, as well as any CROs or tech vendors they work with (www.ema.europa.eu).
- The document explicitly states that these principles *"will underpin future AI guidance in different jurisdictions"* (www.ema.europa.eu), implying that they inform forthcoming regulations in both US and EU.

The Joint Principles also reflect political support at the highest level: the European Commissioner is quoted emphasizing transatlantic cooperation to stay at the forefront of innovation while protecting patient safety (www.ema.europa.eu). The release ties into broader EU initiatives – it cites the European Commission's biotechnology strategy and new pharmaceutical legislation, which explicitly accommodate AI. The Commission proposed the pharmaceutical reform in April 2023, and Parliament adopted its position in April 2024. Parliament and the Council reached political agreement on 11 December 2025; EMA's implementation timeline distinguishes that agreement from entry into force and later application (EMA reform timeline).

Other International and EU Considerations

- **EU AI Act:** Assess each intended use under Article 2 and Article 6. Pharmaceutical use alone does not establish high-risk status: Article 6 uses specified product and third-party conformity-assessment criteria, or listed Annex III uses subject to its exceptions. Distinguish drug-development research tools from medical-device AI and Annex III uses. Article 2(6) excludes systems or models developed and put into service solely for scientific research and development; Article 2(8) excludes specified pre-market research, testing and development, but not testing in real-world conditions. Where applicable, Article 11 and Annex IV govern technical documentation; determine duties according to classification, scope, the operator's role and the applicable date. The Act entered into force on 1 August 2024 and generally applied from 2 August 2026. The Commission's current timeline lists 2 December 2027 for Annex III high-risk rules and 2 August 2028 for high-risk systems embedded in regulated products.
- **ICH Guidelines:** In the EU, ICH E6(R3) (Good Clinical Practice) Principles and Annex 1 have been effective since 23 July 2025. Annex 2 was adopted by ICH and CHMP in June 2026 and becomes effective on 15 January 2027. For example, FDA's CSA guidance has already moved away from "tick-box testing" to focusing on functionality tied to patient risk (www.techscience.com), aligned with ICH Q10's emphasis on quality by design. While we have no AI-specific ICH guideline yet, sponsors can reasonably expect that any new ICH provisions will demand the same level of documentation (change management, validation reports) as for traditional validated procedures.

- **ICH Q9 (R1):** ICH Q9(R1) is final FDA guidance on quality risk management. Applied to AI, this means biases or performance drift identified after deployment must trigger re-validation or updates to the validation state. The FDA and EMA joint principles echo this “lifelong risk vigilance” for AI.
- **Good Manufacturing Practice (GMP) Annexes:** For AI in drug manufacturing, assess applicable drug CGMP requirements, including the computer-system and record controls discussed in FDA’s drug data-integrity guidance. In the EU GMP context, Annex 11 addresses computerised systems. US 21 CFR Part 820 and the CSA guidance concern medical-device production and quality management systems; they do not establish universal requirements for pharmaceutical AI. Annex 11 (2011) requires that any computerized system has documented requirements, specifications, testing and validation, “appropriately defined in protocols, with records of [test] results” (www.techscience.com). For continuous-learning AI deployed in production, Annex 11 would require proof that human oversight and re-validation occur when the system changes.
- **Industry Standards (GAMP5, ISO):** The ISPE’s GAMP5 (2nd ed., 2022) explicitly allows AI and advanced analytics, but only under robust governance. It states that for AI-enabled systems, the emphasis must be on data integrity, documentation, and supplier controls. Likewise, emerging ISO standards (e.g. ISO 42001 on AI management systems, ISO 9001 on QA) can provide a framework for AI quality management, though these are voluntary.

In sum, the international picture converges on familiar themes: **automation assistance is acceptable, but only with full transparency and documentation.** Table 1 compares key regulatory documents and their focus (FDA draft guidance, EMA reflection, EU AI Act, etc.).

Regulatory Body / Framework	Key Documents (Date)	Focus for AI Evidence Packages
FDA (USA)	– Draft Guidance on AI in Drug Development (Jan 2025) (www.fda.gov) – AI/ML Action Plan (2023) – CSA Guidance (final, February 2026) for medical-device production and quality management system software; drug applications may use its methods voluntarily by analogy (www.techscience.com) – 21 CFR Part 11 (Electronic Records) – IMDRF GMLP Principles (2021/25) (www.fda.gov)	– Risk-based **credibility framework**: define Context of Use (COU) for model, pre-specify inputs/outputs and acceptance criteria (www.fda.gov). – Comprehensive model documentation: architecture, training/validation datasets, performance metrics, version history. – Assess predicate-rule retention/submission obligations and regulated electronic-record use before selecting Part 11 controls. – Assess other applicable GxP requirements for the intended use (www.techscience.com).

Regulatory Body / Framework	Key Documents (Date)	Focus for AI Evidence Packages
EMA (EU)	– Reflection Paper on AI (Sept 2024) (www.ema.europa.eu) – EMA–FDA AI Guiding Principles (Jan 2026) (www.ema.europa.eu) – EU AI Act (Reg. 2024/1689) – Annex IV requirements (artificialintelligenceact.eu) – EU GMP Annex 11 (revised 2011) – EMA Guidelines on Pharmacovigilance, GCP, etc.	– Emphasize **existing GxP frameworks**: require AI systems to meet all Quality, safety, and data integrity laws as if non-AI tools (www.linkedin.com) (www.techscience.com). – Documentation of AI processes: data provenance, bias assessment, validation tests, explainability. – EU AI Act: detailed technical documentation (purpose, design, data, testing, risk mgmt, post-market monitoring) for high-risk AI (artificialintelligenceact.eu). – Human accountability: clear logs of who approved model results and when (Annex 11 traceability) (www.techscience.com).
Joint/International	– ICH Q9(R1) (final FDA guidance) – ICH E6(R3) (EU: Principles/Annex 1 effective 23 July 2025; Annex 2 adopted June 2026, effective 15 January 2027) – GAMP5 (2022) – WHO/IMDRF Papers on AI	– Risk-based validation principles across jurisdictions (ICH Q9: risk management throughout lifecycle). – GAMP5: encourage AI use only with rigorous governance and documentation (www.techscience.com). – GMLP/IMDRF: good practices for training data, algorithm updates, human oversight.

Table 1: Selected regulatory and guidance documents relevant to AI validation evidence in pharmaceutical development, and their implications for evidence packages. Citations indicate primary sources.

Good Machine Learning and Validation Practices

In addition to regulators' own guidance, industry and consortia have articulated **Good Machine Learning Practices (GMLP)** to guide AI validation. The FDA and other agencies have endorsed these non-binding principles. Key elements include: ensuring high-quality, representative training data; controlling for bias; making code and algorithms reproducible; rigorous testing; and planning for post-deployment monitoring (www.fda.gov) (www.techscience.com).

For example, the 2021/2025 IMDRF GMLP document outlines 10 principles (e.g. Multi-disciplinary teams, use of trustworthy data, human oversight). While focused on medical devices, these translate to pharma AI: **data governance** is as important as algorithm. A model is only as good as the data used to train it, so a validation package must document the data lineage (source databases, extraction date, preprocessing steps, filtering criteria, etc.) (www.techscience.com) (artificialintelligenceact.eu). Sponsors should apply ALCOA+ principles (Attributable, Legible, Contemporaneous, Original, Accurate, plus Complete, Consistent, Enduring, Available) to all AI-related records, just as for any critical data.

Moreover, human oversight remains central. Algorithms may highlight signals, but experts must interpret and verify them. The "human-in-the-loop" (HITL) model is the safest approach: AI produces hypotheses, humans confirm decisions (www.techscience.com). This was demonstrated in one study where AI-assisted validation ("paperless GMP validation") reduced cycle time by 32% while preserving accuracy, because validation

engineers reviewed every AI recommendation and stored the combined results in **“evidence packs”** (www.techscience.com). Such evidence packs – aggregating the AI output, the human decision rationale, and the audit trail – are precisely the kind of documentation inspectors expect.

Finally, organizations often integrate AI into their existing Computer System Validation (CSV) programs. FDA’s final February 2026 CSA guidance recommends risk-based software assurance for medical-device production and quality management systems. Drug applications may use these methods voluntarily by analogy. For AI, that means validation must not end at initial approval: periodic re-validation or “challenge tests” are recommended to catch model drift (changes in performance over time) (www.techscience.com). Any change to the model (new data, algorithm updates) should be managed under Change Control and requalified. Traceability matrices are used to link user needs to AI model testing, ensuring nothing is left untested (www.techscience.com).

Components of an AI Validation Evidence Package

A thorough AI validation package in a regulatory submission is analogous to a traditional software validation dossier (URS, IQ/OQ/PQ, test reports), but with extra layers for AI. Table 2 outlines the key content elements that should be included.

Evidence Component	Description / Content	Relevant Regulations & Guidance
Context of Use (COU) Statement	**Detailed description of the model’s intended purpose and scope.** Specifies how/where the AI output will be used (e.g. prediction of PK parameters, subgroup detection, imaging analysis) and what decisions it supports. Includes operational boundaries and acceptance criteria.	FDA Draft Guidance (nonbinding COU recommendation) (www.fda.gov). EMA Reflection (model purpose). ICH Q9 (risk assessment context).
System Requirements / Specifications	Documented **User Requirements Specification (URS)** and **System/Software Requirement Specification (SRS)** for the AI tool. Includes functional specs (input-output behavior), performance specs (accuracy targets, sensitivity/specificity), and constraints (runtime, interfaces). Covers both software (algorithm) and hardware risks (e.g. server reliability).	FDA’s CSA (focus on requirements tied to patient safety) (www.techscience.com). Annex 11 (computer system validation protocols). 21 CFR Part 820 (if device).
Development and Training Logs	**Traceability of data and model development:** - Versions of algorithm code (with change logs) - Detailed **training dataset descriptions** (sources, size, years, inclusion/exclusion criteria) - Data preprocessing steps, augmentation, labeling procedures - Model hyperparameters and architecture (e.g. network topology) - Training history (convergence plots, epochs) and tuning records. These ensure reproducibility of model development.	IMDRF GMLP (data quality) (www.fda.gov). EU AI Act Annex IV (training process docs) (artificialintelligenceact.eu). FDA Guidance (data provenance).

Evidence Component	Description / Content	Relevant Regulations & Guidance
Validation/Testing Protocols	**Validation Plan:** test strategy aligned to COU. Includes - Test datasets and methods (withhold data, cross-validation details) - Performance metrics (e.g. AUC, MAE, confusion matrices) and acceptance criteria pre-specified. - Stress/performance tests (edge cases) - Software change control for model updates. - For adaptive models, plan for monitoring and re-validation intervals.	FDA draft AI guidance (context-specific model evaluation recommendations; nonbinding). CSA (focus on critical risks). GAMP5 (V&V protocol). EMA reflection (monitoring AI changes).
Validation Results and Reports	**Test results:** Detailed reports of all validation experiments. - Quantitative performance outcomes with statistics (CIs, p-values if needed). - Comparisons vs. benchmarks (e.g. clinician performance). - Bias and fairness analysis (performance across demographic subgroups). - Usability/human factors results if applicable. - Software testing (unit tests, integration tests) for the implementation code. - Defect tracking and resolution. `All results are signed, dated, and version-controlled.`	21 CFR Part 11 (signed electronic records). ICH Q2(R1) (analytical method validation analogy). Annex 11 (testing documentation).
Risk Assessment and Mitigation	**Failure mode analysis:** Document known risks and how mitigated. - Hazard analysis (especially for patient-level decisions). - Algorithmic Risk Management: plan for model errors, bias suppression, data integrity. - Change control records for any modifications. - Documentation of Data Integrity (ALCOA+) for all inputs/outputs.	ICH Q9/Q10 (risk management). FDA Guidance (credibility includes risk). FDA Data Integrity and Compliance With Drug CGMP guidance.
Operational System Validation	**Computer System Validation (CSV) documentation:** covers the IT environment running the AI. - IQ/OQ/PQ protocols for software/hardware installation. - Audit logs showing who accessed/modified model. - Backup and recovery plans for AI system. - Security and access controls (especially for patient data compliance). - Assess predicate-rule retention/submission obligations and actual regulated electronic-record use before identifying applicable Part 11 record and signature controls.	21 CFR Part 11 (where applicable after record-specific assessment). EU GMP Annex 11 (CSV requirements). FDA Device Rule for cybersecurity.
Traceability Matrix	A matrix linking all **user requirements** to corresponding validation tests and evidence (including code reviews, test scripts, risk controls). Demonstrates that every stated requirement (e.g. “90% sensitivity for Condition X”) was explicitly tested and met.	GAMP5 (requires traceability). Annex 11 (requires proof of coverage of requirements). FDA CSA (focused testing).
Evidence Summary (Inspection Pack)	A top-level document summarizing the above elements. Often includes: - Workflow of AI tool with version IDs - “RACI” chart (responsibility assignments) - Copies of key evidence (signed reports, code snippets, data provenance tables) - Narrative of validation approach and outcomes - Justification of why documentation is “complete.” The “evidence pack” is assembled for inspectors, ensuring they see decisions, signatures, and supporting data in one place (www.techscience.com).	21 CFR 11 & Annex 11 (require inspectors’ evidence). FDA Draft Guidance (documentation emphasis). HITL AI literature (evidence pack concept) (www.techscience.com).

Table 2: Core components of an AI validation evidence package for FDA/EMA submissions, with examples of content and related regulatory references. (COU = context of use; RACI = Responsible-Accountable-Consulted-Informed matrix.)

Each component above corresponds to documents that regulators expect in an eCTD or equivalent submission. For example, the **Validation Results Reports** would populate Module 2 (summaries) and Module 5 (clinical study reports) of an eCTD, while the **Operational System Validation** files fit Module 1/3 (regional electronic records compliance) or separate device submissions.

Notably, **Module 4 (nonclinical study reports)** may now include "computational study reports" when AI was used in preclinical modeling (see FDA's **Draft Guidance on Computational Modeling**). And comprehensive **module 2 narratives** will incorporate AI justifications and summaries (as illustrated by recent training materials for AI-submission cases (pharmacystandards.org)). In practice, the AI evidence package is a subset of the broader submission documents, but with explicit cross-referencing.

Data and Algorithm Validation

A major focus of evidence is **data quality and relevance**. Sponsors must demonstrate the data used to train AI is "fit for purpose" – relevant to the COU – and collected under rigorous conditions. FDA's credibility model emphasizes "contextualized" data: data that is representative of the target population or process (pmc.ncbi.nlm.nih.gov). For instance, if an AI model predicts pediatric adverse events, the training data should include pediatric cases, or else its limitations are documented. The provenance of each dataset must be recorded (source systems, dates, curation steps) and any permissions or patient consents noted (for human data).

Training and test datasets themselves become regulatory evidence: labelled with quality attributes, partitioned by random seed, and stored so results are reproducible. FDA expects an AI developer to treat the entire training pipeline as validation-critical. For example, if transferring data from an electronic health record, the process must be validated to ensure no data corruption (computing environment documented, ETL scripts verified). Sponsors should provide log files or snapshots of raw vs processed data to prove integrity. This thorough data documentation parallels the **clinical trial source documentation** that regulators normally review (pmc.ncbi.nlm.nih.gov).

On the **algorithm side**, one should furnish enough technical detail to allow an informed reviewer to evaluate the approach. This typically means describing the model type (e.g. random forest, neural network architecture), hyperparameter choices, and software version (framework/library) used. While proprietary code may be accepted, regulators often ask for source code or executable versions to review (especially if the AI is central to outcome). FDA guidance notes that for *high-risk applications*, sponsors may be asked to submit model architecture and training logs as part of the regulatory dossier (pmc.ncbi.nlm.nih.gov). EU regulators likewise, under the AI Act, will demand design specifications and version records (artificialintelligenceact.eu).

Validation testing must include both **statistical performance** and **edge-case safety checks**. For example, if an AI decides on medication doses, worst-case inputs (extreme lab values) should be tested. Performance is judged by pre-set metrics: classification accuracy, calibration, etc. FDA's draft urges that a sponsor define

acceptance criteria in advance – e.g. “the model must achieve ≥90% agreement with expert review on primary endpoints.” Any unplanned findings (like unexpected biases) should be documented in source notes.

Bias and fairness evaluation is also emerging as expected evidence, especially since FDA has highlighted drug trial diversity as a priority (21st Century Cures Act). If an AI was trained on clinical trial data, sponsors should analyze its outputs across demographic subgroups. A fairness report should assess subgroup performance on independent test data and report performance estimates with confidence intervals (FDA draft guidance). Do not base a conclusion of adequate fairness solely on p>0.05: statistical conclusions should not depend only on whether a p-value passes a threshold (ASA statement).

Human Oversight and Governance

Regulators stress that **human responsibility cannot be delegated to AI** (www.techscience.com). In practice, this means any AI-supported decision in a submission must show who made the final call. Evidence should show that humans reviewed model suggestions: a signed review by a qualified person, with date and rationale. This could be implemented via electronic forms in the workflow or annotations in a system.

For an AI-supported bioequivalence analysis, determine the applicable study-specific approval, record and signature requirements before choosing an electronic sign-off workflow; Part 11 applicability depends on predicate rules and regulated record use. In the evidence pack, these signatures and decision logs are crucial. [Amin 2026] describes explicit “rationale cards” and e-signature checkpoints in the AI validation workflow that capture *who* and *why* approvals were made (www.techscience.com). Table 2 above lists an “Evidence Summary” element precisely to consolidate these audit-relevant items.

Governance documents should accompany the evidence package. These include standard operating procedures (SOPs) for AI model development and change control, a *Risk Tiering* classification (e.g. “Model X is high-risk because it affects primary endpoint evaluation”), and possibly a RACI matrix showing roles (who is Responsible/Accountable/Consulted/Informed at each step) (www.techscience.com). Regulatory authorities appreciate seeing that a pharmaceutical quality management system (QMS) has incorporated AI into its change management and monitoring processes.

Traceability and Audit Trails

Both FDA and EMA reiterate the importance of traceability. EU Annex 11 explicitly requires that “persons who assess or approve computerized system validation must be documented” and that audit trails for electronic records are preserved (www.techscience.com). In practical terms, AI development platforms and validation tools should have audit logs of code changes, test results, data modifications, etc. These logs are part of the evidence package.

A robust traceability matrix (linking requirements to tests) is very useful. Table 2 includes this as a line item. For instance, if one URS states “Algorithm shall achieve 90% sensitivity on dataset X”, the matrix would reference the specific test case that measured sensitivity on X and the report showing it passed. This provides clear evidence to an auditor that *nothing is undocumented*.

The concept of **evidence packs** operationalizes this. An inspector typically wants to see *how* a decision was made, who signed it, and what data supports it (www.techscience.com). An evidence pack collects: (1) the AI's original output (e.g. a graph or list of predictions), (2) the human reviewer's annotated decision and comments, and (3) metadata (timestamps, version IDs). Presenting this as a cohesive package lets regulators follow the entire chain of custody for each AI-driven conclusion (www.techscience.com). In fact, [Amin 2026] notes that such packs "make life easier for SMEs and auditors" by assembling the story of a decision in one place (www.techscience.com).

Comparative Focus: FDA vs EMA

Although FDA and EMA have been aligning, there are minor emphasis differences. A non-exhaustive comparison:

- **Scope of Guidance:** FDA's January 2025 draft is narrowly focused on AI used to support regulatory decision-making about drugs/biologicals. It even explicitly excludes AI for operational efficiency tasks (scheduling, etc.) (www.linkedin.com), which it sees as outside scope. EMA's Reflection has a broader purview (entire lifecycle including post-market), but similarly characterizes purely administrative AI as lower priority. Both say core regulations still apply to everyone.
- **Documentation Expectations:** Both regulators demand documentation, but EMA's approach (so far) is more principle-based. The EMA Reflection refrains from listing specific required items in one place, instead weaving documentation expectations into discussion (e.g. "vendors should maintain evidence of data quality"). The FDA draft is more structured, implying sponsors should prepare explicit deliverables (like an algorithmic development report, similar to a nonclinical study report). EMA's reflection paper provides considerations for regulatory evaluation; the level of scrutiny depends on the system's risk and regulatory impact (EMA reflection paper).
- **Data Privacy and Ethics:** EMA explicitly weaves GDPR considerations into its AI discussions (e.g. anonymization of patient data in AI training). The FDA does not have an equivalent centralized data privacy law, so its guidance focuses more on integrity. On ethics and bias, both agencies note demographic fairness, but EMA (and EU law) may impose stricter data usage rules. For instance, under EU AI Act, demonstrating data representativeness and bias mitigation is mandatory for high-risk AI.
- **Engagement and Timelines:** FDA's guidance remains at draft stage (as of early 2026) and will be revised. EMA's Reflection is adopted, but any binding EMA guideline will take time. The joint principles signal that more formal EMA and FDA guidelines are "in the pipeline". Sponsors in the EU can also leverage Innovation Task Force (ITF) meetings to discuss novel AI methods. In the US, FDA's C3TI focuses on clinical trial innovation. For other AI uses, select an FDA engagement option appropriate to the intended use.

Nevertheless, the **bottom line is very similar**: both expect *risk-based, transparent validation with documentation*. A company preparing an AI evidence package can largely use one strategy to meet both, adding a few jurisdictional specifics (e.g. reference Annex 11 for EU documents, cite FDA guidance for US rationale). Table 1 and Table 2 attempt to harmonize these points.

Data and Evidence Analysis

Quantitatively, the literature on AI in pharma is burgeoning. A 2025 survey (Tufts/TransCelerate et al.) reported widespread use of AI models across multiple drug development functions (pmc.ncbi.nlm.nih.gov). Clinical trial design and planning (e.g. virtual cohorts, synthetic control arms) and data analysis (e.g. text mining of literature or patient records) were especially cited. Another 2024 scoping review found numerous case reports of AI improving trial recruitment or EMR phenotyping (even if not all were regulatory sponsors) (pmc.ncbi.nlm.nih.gov).

From a regulatory standpoint, FDA's count of "500+ AI-enabled submissions since 2016" (www.fda.gov) is one measurable indicator of prevalence. For comparison, ICH E6(R3) Principles and Annex 1 have been effective in the EU since 23 July 2025; Annex 2 was adopted by ICH and CHMP in June 2026 and becomes effective on 15 January 2027. Investment projections (PwC's $16B by 2034 (www.pwc.com)) underscore industry commitment. One can foresee that in a few years, dozens of new drug applications will incorporate AI-derived endpoints or in silico substantiation.

Case studies illustrate both benefit and peril, underscoring the need for solid evidence:

- **Independent model evaluation:** FDA's draft AI guidance recommends that test data be independent of development data and withheld from the algorithm during training (FDA draft guidance).
- **AI in Labeling and Diagnostics:** Although more peripheral to pharmaceutical products, there are analogous examples from medical devices where AI claims require formal validation. For instance, companies have obtained FDA clearance for AI diagnostic tools (e.g. in radiology) by supplying datasets and performance results similar to those expected for drugs. This cross-pollination shows the FDA is comfortable reviewing algorithmic evidence when it is comprehensive.

In aggregate, these examples illustrate the stakes. AI can definitely reduce time and increase insight (e.g. 25–40% faster validation cycles reported when AI-assisted tools were used in GMP validation (www.techscience.com)). But to secure that benefit, sponsors must present **thorough evidence** that AI tools were governed at least as rigorously as any other critical method.

Implications, Best Practices, and Future Directions

The emerging regulatory landscape has major implications for pharma companies, CROs, and AI vendors:

- **Early Planning and Documentation:** AI projects should be initiated with regulatory compliance in mind. Just as one engages quality assurance early for a new manufacturing process, companies should establish AI **validation plans** at project start. These plans should mirror the evidence components above: data management protocols, software development lifecycle documentation (SOPs), and predefined validation milestones. This way, regulatory deliverables are generated concurrently with development, not retroactively.

- **Multidisciplinary Teams:** Meeting AI evidence requirements often requires teams fluent in both ML and regulatory paradigms. Sponsors may need to involve pharmacometricians, statisticians, AI specialists, and pharmacovigilance/regulatory experts together. Industry consortia (e.g. C-Path, TransCelerate) are creating working groups precisely to bridge these silos (pmc.ncbi.nlm.nih.gov). The example of HITL AI frameworks shows the value of combining AI engineers with QA/QC staff (www.techscience.com).
- **Governance and Quality Systems:** Quality departments must adapt. Traditional CSV and IQ/OQ/PQ templates should be revised to include AI-specific checks. For instance, change control forms should consider "updates to AI model parameters" as a type of change requiring review. Audit teams should be trained to audit AI processes: for example, how do you audit a machine learning model? The software community is developing guidelines (see **"AI Navigator" Annex usage summaries (artificialintelligenceact.eu)), but pharma needs to embed AI into its existing QMS.
- **Model Transparency vs. IP:** One tension is between sharing enough details for validation and protecting intellectual property. Regulators favor transparency but are generally willing to allow trade secrets (e.g. exact neural network weights) if the sponsor provides a way to audit performance. Companies may submit model code under confidentiality (or access in a secure zone). However, at minimum, clear descriptions of methodology and independent verification of results are expected.
- **Audit Readiness:** Documentation should be *inspection-ready*. This means not just having the evidence on file, but organizing it clearly. A recommended practice: include an **executive summary document** in the submission introduction (CTD Module 2) that specifically lists all AI-related items (e.g. "Appendix 10.1: AI Model Validation Report, signed by Study Director"). Ensure cross-references and version stamps are unambiguous.
- **Vendor Qualification:** If using third-party AI tools (e.g. cloud ML services, commercial models), they become "suppliers" under GMP. Quality agreements must cover software validation support, and vendors may need to provide documentation of their own validation activities. Some companies are already requiring certificates of analysis for AI models, similar to how raw material vendors supply certificates.

Looking forward, we expect further developments:

- **Guidance development:** FDA's January 2025 AI guidance remains listed as a draft, not for implementation (FDA guidance status). In the EU GMP framework, the Commission held a consultation from 7 July to 7 October 2025 on revised Chapter 4, revised Annex 11 and new Annex 22 on Artificial Intelligence. The consultation identifies these as drafted documents; distinguish that development process from adopted requirements (Commission consultation).
- **AI in Post-Market Surveillance:** Regulators will focus on how AI tools perform in the real world. We may see requirements for post-approval monitoring of AI performance (much as new drugs have Phase 4 commitments) – e.g. annual reports on model accuracy drift. The EMA Reflection hints at the need for feedback loops to update AI algorithms after deployment, under regulatory review.

- **Expansion to Other AI Categories:** The current focus is on AI for *decision-making data*. But what about generative AI (e.g. LLMs) used in documentation or drafting? FDA's draft excluded purely operational uses, but real-world companies are using LLMs for e.g. writing protocols. We anticipate future guidance on AI in decision support and operational roles separately – likely requiring robust internal validation even if "not for decision-making" under current guidance.
- **Ethical and Diversity Considerations:** Societal demands for fairness may soon translate into regulatory checklists. The U.S. has fewer formal equity requirements than the EU, but given the attention on trial diversity, we may see the FDA requiring a diversity statement or impact analysis whenever AI was used for patient selection. The EU, via the AI Act, will enforce transparency and non-discrimination as mandatory for high-risk healthcare AI (artificialintelligenceact.eu) (pmc.ncbi.nlm.nih.gov).
- **Education and Workforce:** A broader implication is the need for upskilling: regulatory reviewers themselves are learning AI. FDA's new "AI in review" training programs and EMA's data scientists reflect this. Industry regulatory affairs professionals will similarly need deeper understanding of AI. We foresee more workshops and possibly certifications in AI regulation (as already emerging in bioinformatics).

Conclusion

As AI becomes pervasive in pharmaceutical development, generating credible evidence of its reliability is paramount. Both the FDA and EMA have signaled that **transparency, risk management, and documentation** will be central to regulatory acceptance of AI. Sponsors must transition from treating AI as an afterthought to embedding it in their validation ecosystems from day one. This means rigorous data governance, multidisciplinary oversight, and meticulous record-keeping – essentially, treating AI outputs with the same level of scrutiny as any experimental result.

Key takeaways from this analysis include:

- **Regulatory Convergence:** US and EU authorities are largely aligned in principle. Both demand context-specific, risk-based validation of AI models, and insist that operators retain accountability. The shared "Good AI Practice" principles underscore this commonality (www.ema.europa.eu).
- **Evidence Package Essentials:** An AI evidence package should include clear definition of COU, complete documentation of data and algorithms, thorough test reports, risk analyses, and audit trails. Emerging best practices like "evidence packs" help ensure that regulators can easily verify every decision (www.techscience.com). Sponsors should reference authoritative sources (FDA draft guidance, EMA reflection, AI Act Annex IV) in their submission to show alignment.
- **Preparation and Engagement:** Proactive preparation is critical. Before using an AI tool, companies should develop SOPs and training for staff, and engage regulators through the proper channels (FDA pre-IND meetings, EMA Scientific Advice). Regulatory reviewers have indicated a willingness to provide feedback on AI plans, but only if presented with a coherent, well-documented proposal.

- **Technology for Compliance:** Interestingly, AI itself can aid compliance. Tools that track data lineage or monitor AI bias can be part of the solution. But ultimately, the “paper trail” remains a human responsibility. The recent academic demonstration that AI-augmented validation can improve efficiency – *only when structured with human review and governance* – illustrates this synergy (www.techscience.com).

In conclusion, documenting AI validation for FDA and EMA dossiers is a demanding yet manageable task if approached systematically. It requires combining established pharmaceutical validation principles with adaptations for AI’s iterative nature. This report has sought to comprehensively catalog those requirements and guide companies in constructing their documentary proof. As regulators continue to refine guidance and as technology evolves, the core tenet will endure: **Trust in AI must be earned with thorough, auditable evidence**. With the right evidence package, AI can become a certified and celebrated part of the path to new therapies.

Source links

Links cited in this article, in order of first appearance. Full addresses are provided for readers using extracted text.

1. https://www.fda.gov/news-events/press-announcements/fda-proposes-framework-advance-credibility-ai-models-used-drug-and-biological-product-submissions
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