Good AI Practice and the Regulatory Lifecycle

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Artificial intelligence is becoming an integral part of drug development, including regulatory work. As adoption expands, regulatory expectations are becoming clearer and more defined.

In January 2026, the FDA and EMA released Guiding Principles of Good AI Practice in Drug Development, outlining a shared framework for responsible AI use across the therapeutic lifecycle. The principles emphasize human oversight, defined context of use, structured governance, and lifecycle continuity.

For drug development leaders, this guidance signals something important: AI must operate within the same rigor and structure as the submissions it supports.

At Weave, this perspective aligns closely with how we build AI for regulatory work. We approach AI not as an overlay, but as infrastructure designed to integrate directly into real regulatory processes and support expert judgment from Pre-IND strategy through NDA or BLA preparation.

A Shared View of Responsible AI

The FDA's guiding principles reinforce a central idea: AI should strengthen teams without obscuring accountability or decision-making.

AI can reduce friction, improve consistency, and help manage complex documentation across programs. But it must do so in a way that preserves transparency, traceability, and regulatory integrity. The principles offer a practical lens for evaluating whether AI is being applied thoughtfully in high-stakes regulatory environments.

Human-Centric, Risk-Based Design

The framework begins with two foundational concepts: human-centric design and risk-based application.

Responsible AI in regulatory development keeps experts firmly in control. Technology can support structuring information, aligning documentation to eCTD module expectations, and drafting within defined workflows. Strategy, scientific interpretation, and regulatory positioning remain guided by experienced professionals.

AI is most effective when applied selectively. High-friction, lower-risk documentation tasks benefit from structured automation. Critical scientific and strategic decisions remain under human oversight.

Clear Context of Use and Alignment with Standards

AI systems must be purpose-built and grounded in the environments in which they operate.

In regulatory settings, this means reflecting established submission structures, documentation patterns, and review expectations. Alignment with eCTD organization and structured review processes is not optional — it is foundational.

Purpose-built regulatory AI differs meaningfully from generic automation tools. Context matters. Systems designed specifically for regulatory lifecycle management are better positioned to support consistency, continuity, and auditability across programs.

The guiding principles highlight the importance of multidisciplinary expertise in both AI development and deployment.

Effective AI solutions must support collaboration within a structured regulatory environment. Scientists, regulatory leaders, and operational teams should be able to contribute within a shared framework that maintains consistency across contributors and milestones while preserving clear accountability.

Governance, Lifecycle Management, and Transparency

Trust in AI depends on traceability and continuity.

Regulatory documentation evolves over time. Early planning informs IND development. Health authority interactions shape subsequent updates. Later-stage preparation builds on institutional knowledge accumulated across the lifecycle.

Responsible AI systems must preserve structured document history, version tracking, and source alignment so teams can see how narratives evolve. As data changes and regulatory questions arise, documentation can be refined without fragmenting prior work.

Clear visibility into how content is assembled and refined is equally critical. Transparency enables informed oversight and reinforces confidence in the outputs generated.

Responsible AI in Practice

The FDA's guiding principles reinforce an important message: responsible AI in drug development is not defined by speed alone. It is defined by transparency, structure, and informed human judgment across the regulatory lifecycle.

At Weave, these principles are foundational. By building AI that is human-driven, purpose-built, and aligned with regulatory reality, we aim to support drug development teams with greater clarity and confidence from early development through submission milestones.