



FDA REGULATION OF AI IN LIFE SCIENCES

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AI Opportunities in Life Sciences Continue to Grow as FDA Frames its Regulatory Approach

As rapid technological advances continue to spur investments in Artificial Intelligence (AI) tools for use in the life sciences, FDA continues to refine its framework for the use of AI to support regulatory decision-making for drugs, biologics, and medical devices throughout the product life cycle.

AI tools have the potential to impact virtually every stage of the life sciences product life cycle, offering the opportunity to enhance operational efficiency, to optimize data analysis, and to improve error detection. A recent [report](#) from the McKinsey Global Institute estimates that Generative AI (GenAI) alone—which the United States Food and Drug Administration (FDA) [defines](#) as a “class of AI models that emulate the structure and characteristics of input data in order to generate derived synthetic content”—could unlock US\$60 to US\$110 billion a year across the life sciences value chain, including US\$15 to US\$28 billion in R&D, and US\$13 to US\$25 billion in clinical development.

On January 6, 2025, FDA ramped up efforts to articulate its framework for the use of AI in regulatory decision-making, issuing a pair of draft guidance documents focused on drugs, biologics, and medical devices:

- [Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products](#) provides (1) recommendations on the use of AI to support FDA regulatory decision-making regarding safety, effectiveness, or quality for drugs, and (2) a risk-based credibility assessment framework that may be used for establishing and evaluating the credibility of an AI model for a particular context of use (COU).
- [Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations](#) provides a “comprehensive approach” to the management of risk throughout the device total product life cycle (TPLC), including recommendations on the content of marketing submissions for devices that include AI-enabled device software functions and recommendations for the design, development, and implementation of AI-enabled devices throughout the TPLC.

Public comments on both guidance documents are due by April 7, 2025.

As detailed in our recent [Fireside Chat](#) with former FDA Commissioner Dr. Scott Gottlieb, recent AI use cases span the product lifecycle, and include drug discovery and development, clinical trials, manufacturing, and pharmacovigilance and adverse event reporting, as well as AI-enabled software. Key takeaways include:

1. Discovery and Development

AI tools have the potential to shorten the process of identifying agents and predicting which might be good candidates for clinical development. Not only are AI tools capable of suggesting a viable drug candidate, but they also are capable of providing a sound biological rationale for its selection. The use of AI tools in the development process thus has the potential to facilitate the regulatory review process if used appropriately.

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2. Clinical Trials

AI tools have widespread applications for clinical trials. AI can be used to improve data management, to process large volumes of trial data quickly, and to identify trends and insights, while predictive modeling can forecast potential adverse events and efficacy outcomes, supporting informed decision-making.

Companies also can leverage AI tools to enhance the diversity of clinical trials, an area of focus for FDA. For instance, GenAI can analyze vast datasets to identify underrepresented populations that meet the criteria for clinical trials.

3. Manufacturing

In the manufacturing sector, AI offers significant opportunities for increased efficiencies and quality. By analyzing manufacturing processes, AI (including GenAI), can identify areas for improvement, enhancing efficiency, yield, and quality control. For example, companies are beginning to use AI to forecast equipment failures, for visual inspections, and to assist with deviation investigations.

4. Pharmacovigilance and Adverse Event Reporting

Companies also can deploy AI tools to enhance pharmacovigilance and adverse event reporting processes. For example, AI tools can analyze real world data (RWD) to detect and predict adverse drug and device events. AI-enhanced monitoring may facilitate the early identification of safety signals, improving the speed and accuracy of pharmacovigilance activities.

5. AI-Enabled Software Products

Companies also are developing AI-enabled software products that healthcare providers, consumers, and patients may use to improve health. Use cases include the use of AI in telehealth and clinical decision support software, as well as to support device hardware. A key threshold regulatory question for companies is whether their products would be considered a medical device that require marketing authorization before commercialization.

To date, FDA's Center for Devices and Radiological Health (CDRH) has [authorized over a thousand AI-enabled](#) medical devices for marketing in the United States. Importantly, however, FDA has yet to approve, authorize, or clear a GenAI-enabled product as a medical device. FDA held its first Digital Health Advisory Committee meeting in November 2024, where generative AI was a focus and FDA noted that "special controls" may be needed for GenAI enabled medical devices.

In addition, FDA has started to increase enforcement efforts regarding marketing claims made about AI-enabled products, and to review the use of AI during regulatory inspections. Understanding these trends is important as companies consider use cases.

The Future of AI at FDA

In the future, we predict that nearly every life sciences company will be an "AI company" and use AI in some application during the product lifecycle. By identifying such opportunities now and anticipating potential areas of regulatory focus, companies can leverage AI tools to achieve greater efficiency and position themselves for future success.

FDA's approach to AI has highlighted the importance of transparency and mitigating bias, robust validation, and postmarket monitoring, and overall emphasized a total product lifecycle approach. The federal government's, and FDA's approach, will continue to evolve with the new administration and potential new executive orders.

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