
The Regulatory Lifecycle + AI

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Artificial Intelligence (AI) is transforming industries, and drug development is no exception. The regulatory lifecycle, a critical part of therapeutic drug development, offers numerous opportunities for AI to streamline processes, reduce errors, and accelerate time to market. How do you effectively incorporate AI into this complex lifecycle? It requires a thoughtful approach and a clear framework to ensure success, which we present here as five key elements.

Let's examine the five key elements to consider when integrating AI solutions into the regulatory lifecycle.

1. Ensure Simplicity and Intuitive Use

The regulatory process in drug development is already highly complex. The AI tools you introduce should simplify, not complicate, your workflows. When choosing an AI solution, it's essential to focus on simplicity and ease of use. Your teams—regulatory affairs, scientists, and leadership—need a tool that is intuitive, interactive, and doesn't require extensive training to operate.

The goal is to allow your teams to focus on high-level tasks like interpreting data, strategizing submissions, and ensuring regulatory compliance, while the AI handles the more tedious, time-consuming work such as data gathering, drafting content, and organizing documents.

2. Select AI-Native Solutions

Not all AI platforms are created equal. Some systems may have AI added on as an afterthought, while others are AI-native, meaning they have been designed from the ground up with AI as a foundation. AI-native tools leverage AI throughout their workflows, often subtly, to make your work faster and easier. They are built to create value for their users, not show off the technological prowess of their builders.

When considering AI for regulatory processes, it's important to choose AI-native solutions. These systems are better equipped to handle complex workflows and can offer meaningful automation that enhances productivity throughout the lifecycle. AI-native platforms embed intelligent automation directly into your processes, helping reduce submission errors and accelerate regulatory timelines.

3. Look for Purpose-Built AI Tools

General-purpose AI systems may be useful for many tasks, but when it comes to the regulatory lifecycle, you need tools that are specifically built to address the unique challenges of drug development. Regulatory submissions, such as Investigational New Drug (IND) applications, require handling enormous amounts of complex, technical data, and the stakes for accuracy are high.

Choosing a purpose-built AI solution ensures that the tool is tailored to the regulatory environment. These solutions can handle everything from summarizing scientific reports to constructing complex tables and organizing vast amounts of clinical data. Purpose-built AI tools understand the intricacies of the regulatory lifecycle and are designed to work within that framework to improve accuracy and speed.

4. Prioritize Process Awareness and Adaptability

Every organization's drug development process is different, and the AI solution you choose should be adaptable to your specific regulatory workflow. AI tools that are aware of your particular

processes will require less manual configuration and integrate more seamlessly into your operations.

When selecting an AI solution, look for one that can manage tasks specific to regulatory submissions—like collecting data from various departments, generating draft content for submission documents, enabling iterative reviews, and preparing documents for submission to regulatory bodies. This level of process awareness reduces the burden on your team and ensures that AI is adding real value to the lifecycle, not creating additional steps or obstacles. Also, by being process-aware, the need to interact with multiple platforms or transfer data between them is reduced, streamlining the entire submission process from start to finish.

5. Work with a Nimble and Experienced Partner

Technology is ever evolving. When choosing an AI solution, it's not just about the software itself but also about the company behind it. Your AI partner should be knowledgeable about both AI technology and regulatory processes in therapeutic development.

The company should also be agile, able to quickly respond to changes in technology and regulations, and provide continuous updates to improve the software based on your needs. They should approach AI implementation rigorously, applying scientific and systematic methods to ensure the solution is both reliable and adaptable. A strong, experienced partner will help ensure that your AI solution evolves along with your business and regulatory requirements, enabling you to stay ahead of the curve in a competitive and highly regulated industry.

AI's Growing Role in the Regulatory Lifecycle

With the right AI solution, organizations can automate many of the tedious tasks involved in submissions—like data organization, document drafting, and metadata management—freeing up regulatory teams to focus on higher-value work. AI can also help reduce the risk of errors, improve compliance, and accelerate the time to bring new therapies to market.

While AI has the potential to take on many regulatory tasks, human oversight will always be critical. Strategic decisions, data interpretation, and submission planning still require the experience and judgment of regulatory professionals. AI works best when it is used to augment human decision-making, not replace it.

By following this framework—focusing on simplicity, AI-native solutions, purpose-built tools, process awareness, and choosing the right partner—you can ensure that you are integrating AI into the regulatory lifecycle in a way that adds real value to your process. The right AI solution will not only enhance efficiency but also improve the quality and speed of your regulatory submissions, helping bring life-saving therapies to market faster and more effectively.