Easing compliance with generative AI in healthcare and life sciences

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Life sciences organizations manage a growing set of regulations from multiple agencies, including the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), the Japanese Pharmaceuticals and Medical Devices Agency (PMDA), and other regional bodies. Each has different data requirements, submission formats, and standards.

Compliance teams spend hours retrieving, reviewing, and cross-referencing information, much of it unstructured and scattered across systems. These manual processes are time-consuming and can lead to errors and inconsistencies, which are amplified when the information is used to write, review, and submit required reports.

A modern generative AI (gen AI) solution, such as the Provectus AI Document Manager for Compliance in Healthcare & Life Sciences, changes this dynamic. It can automatically process, categorize, organize, and analyze large volumes of data to satisfy burdensome documentation requirements and compliance rules, while at the same time improving accuracy and consistency. The solution can also flag potential compliance risks and suggest appropriate responses aligned to policy and prior submissions.

Across the board, gen AI enables staff to draft better inspection reports and regulatory narratives, helping to avoid common compliance pitfalls and align to evolving expectations. This results in faster cycle time, higher quality and accuracy, and measurable cost savings.

Built on AWS, with Amazon Bedrock and Amazon Textract at its core, the Provectus solution is layered with custom gen AI capabilities that improve document processing accuracy by 30% to 50% compared to baseline optical character recognition (OCR) workflows. It can also reduce costs by 80% to 90%.

The AI Document Manager handles structured, semi-structured, and unstructured documents, including FDA Form 483s, standard operating procedure files, inspection records, and submission drafts.

By automating the extraction, classification, and management of document data, and streamlining the drafting of compliance narratives, the Provectus solution enables life sciences organizations to respond faster to audit findings, regulatory queries, and inspection reports. It significantly reduces bottlenecks and manual error risks, and shaves weeks off end-to-end compliance workflows.

A built-in “human-in-the-loop” review feature allows compliance teams to validate or correct AI outputs before finalization. Each correction feeds back into the model to improve precision over time, while maintaining the oversight required in regulated environments.

Biotech firm gains business value with document manager

Switching to gen AI-based document processing can produce dramatic results in a short amount of time, as evidenced by the work of Provectus with life sciences consultancy PSC Biotech.

To help the company manage a particularly complex set of FDA requirements, Provectus built a gen AI-powered solution similar to AI Document Manager, using a foundation model hosted on Amazon Bedrock.

The solution, which automatically classifies, extracts, and organizes critical observations from FDA Form 483s, enabled PSC to process 10x more documents than before. Completing compliance workflows is now 90% faster, lowering costs by 44%.

The solution generated a 93% return on investment in just 12 months and is designed to improve the accuracy and consistency of document analysis over time.

The bottom line

Gen AI is also evolving rapidly. AI agents are beginning to interpret regulations, map implications, and trigger workflows, such as updating documents or alerting stakeholders across systems. In the near future, these assistants will likely be able to manage the entire compliance process autonomously. Provectus is closely following these developments to keep its solutions aligned with the latest innovations.

Fast-track gen AI transformation to cut compliance time and cost in your organization. Get started with Provectus on AWS Marketplace.

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