



Case Study

Effective pharma compliance with GenAI

HCLTech helped automate the audit management system for a North American pharmaceutical company

A North American pharmaceutical company partnered with HCLTech to revolutionize their internal audit and reporting processes using GenAI. Their existing rule-based document auditing system proved costly and lacked user-friendliness, prompting the adoption of a GenAI solution integrated with Azure OpenAI and Adobe API. The value delivered through this approach enabled our client to:

95%

Predict gaps in document quality with accuracies over 95%

65%

Reduce manual document development efforts by 65%

50%

Increase readability score by 50%

Audit Management is a vital process for Life Sciences companies to ensure the risks are regularly reviewed with a heightened sense of urgency around compliance to protect patient safety, product quality and data integrity. As part of this process, all software development lifecycle (SDLC) documentation is subject to internal audits.

The Challenge

Redesigning legacy system for elevated user experience

Our client's challenge surrounded rearchitecting their auditing system, which was code and rules-heavy, to a cognitive solution that elevated the experience for authors and auditors. They also wanted to meet the demand for document volume, reduce cost and time constraints on internal auditors and improve tool reliability and user-friendliness.



The Objective

Develop Gen AI-based solutions to make audits more efficient

- Replace the rule-based engine with a Gen AI-powered document auditing system
- Reduce the effort needed to define and modify complex business rules
- Improve system scalability for growing document volumes in SDLC
- Enhance accuracy, reliability and user-friendliness of the auditing tool
- Optimize redevelopment efforts for reduced maintenance and updates



The Solution

Implement intelligent auditing solutions for enhanced accuracy and user experiences

HCLTech developed an Azure OpenAI-based solution to encode complex business rules and identify document gaps in natural language.

- Gaps are summarized using Gen AI and reported as findings with a high degree of accuracy
- A user-friendly interface was developed for adding PDFs and business rules, simplifying audit report generation
- Audit reports, with contextual information, were generated using zero-shot prompting and used for downstream CAPA generation



The Impact

Accurate gap predictions, minimal manual effort and human-friendly experiences

With relentless commitment, we've harnessed cutting-edge GenAI technology and executed their vision with precision. The collaboration between HCLTech and the client has yielded a transformative impact on internal audits and reporting through Gen AI technology.

After the successful deployment of the solution, the results were:

95%

improved gap prediction accuracy, reducing manual auditing

60-75%

less development effort for new document types/rules

50%

higher readability score in gap summaries, making the experience more human-friendly