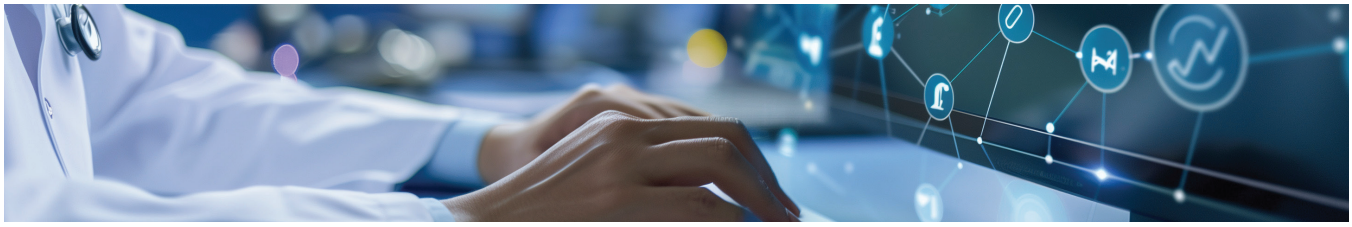
C3.ai

Large Medical Device Company Accelerated R&D Documentation with Generative AI



A leading multinational medical device company serves over 40 million patients annually, delivering life-saving innovations through hundreds of products.

However, as the scale of innovation grows, so does the challenge of maintaining rigorous documentation necessary for regulatory compliance and product safety, with the goal of reducing patient harm. Traditionally, nearly half of the company's R&D budget has been dedicated to meticulous documentation, ensuring each product meets the highest quality standards.

The current process for R&D documentation was complex, manual and not scalable, often taking a trained quality assurance (QA) engineer weeks to complete one document. The QA engineer must evaluate the product from an engineering design perspective, identify its risks and harms to ensure product quality, and assess its usage based on regulatory requirements. The company sought an AI solution to aid the QA engineers and shorten the time required to create R&D documentation, starting with the most critical process for product safety: hazard analysis.

Prior to engaging with C3 AI, the company relied on experienced QA engineers and subject matter experts to produce hazard analysis reports manually. However, this labor-intensive approach was not scalable because it took a long time to hire, train and develop a QA engineer who can help the company to deliver highest quality products, reduce the risk of patient harm and comply to global regulations.

The company partnered with C3 AI for an 18-week pilot of C3 Generative AI to generate hazard analysis and create a scalable solution for broader R&D documentation and business lines.

The company leveraged C3 Generative AI for Documentation Acceleration to automatically produce hazard analysis reports with high accuracy (up to 90%) and minimal review effort from QA engineers, allowing them to focus their time on other complex and high value activities.

In addition to successfully achieving high accuracy, and minimal-hallucination output, C3 Generative AI gained high adoption among QA engineers with simple and intuitive interfaces and workflows. Furthermore, to enhance user trust and increase efficiency, the application provided output relevance checks and full traceability, and generated output in a format compliant to the company's standards.

With C3 Generative AI, the medical device company reduced time to produce hazard analysis by 99%, unlocking massive efficiency again in their risk assessment documentation process.

Project Objectives

- Enable a more streamlined and automatic process for hazard analysis documentation.
- Provide an easy-to-use interface to help QA engineer be more efficient.
- Configure the C3 Generative AI for Documentation Acceleration application that is ready to scale to other use cases across the company.

Results

99%

reduction in time to produce hazard analysis from weeks to minutes

80-90%

accuracy of C3 Generative AI generated hazard analysis documents

Challenges

This company spent around 50% of their R&D budget on documentation ranging from product feature research and risk assessments to manufacturing procedures and distribution guidelines. Hazard analysis was one of the most complex but of highest importance documents to enhance product quality, record potential harms and predict severity and occurrence.

Despite prior efforts, the documentation process remained inefficient and time-consuming. QA engineers spent years learning company specific terms and language (to satisfy regulatory and quality requirements) and wasted days locating disjointed information (historical risk and R&D documentation, predicate products, protocols and compliance guidelines, user feedback, complaints), and working through multiple reviews with subject matter experts to improve the documents.

This resulted in weeks of inefficient efforts and intra-engineer variability in output documentation quality and potential for a lower quality medical device that may result in patient harm.

About the Company

- $15+ billion annual revenue in 2023
- 40+ million patients each year
- $1+ billion R&D investment

Project Highlights

- 18 weeks from kick-off to production-ready application.
- Reduced time to produce hazard analysis by 99% from weeks to minutes
- Achieved up to 90% accuracy.
- Built in robust security features that comply with company's policies and governance frameworks.
- Configured the C3 Generative AI application with an intuitive and seamless user interface.
- Set up the system to be ready to scale to other use cases within R&D documentation value chain and across business lines.

Deploying C3 Generative AI for R&D Documentation Acceleration

Over 18 weeks, C3 AI configured C3 Generative AI for Documentation Acceleration, focusing first on hazard analysis for the Endoscopy division.

A joint team of developers, data scientists and quality engineering subject matter experts identified the corpus of documents required for hazard analysis, the desired output, various input formats, user interfaces and the most efficient workflows. The team designed the approach that incorporated various innovative techniques, such as advanced document processing and chunking to handle non-standard formats and deep learning to inject domain-specific, contextual information. These techniques enabled zero pre-processing work from QA engineers and reliable information retrieval and content generation capabilities that mimic human logics with minimal hallucination.

C3 AI also configured hazard analysis output formats and enabled access controls to tailor to the strict requirements of the company in format compliance and security.

C3 Generative AI for Documentation Acceleration generated hazard analysis reports in minutes (instead of weeks) ready for QA engineers to review with full output relevance traceability and checking. This allowed QA team to further shorten the time to review. The application achieved 80-90% accuracy for hazard

analysis reports and reduced intra-engineer variability, significantly shortening the documentation time and freeing up QA time for other higher value tasks.

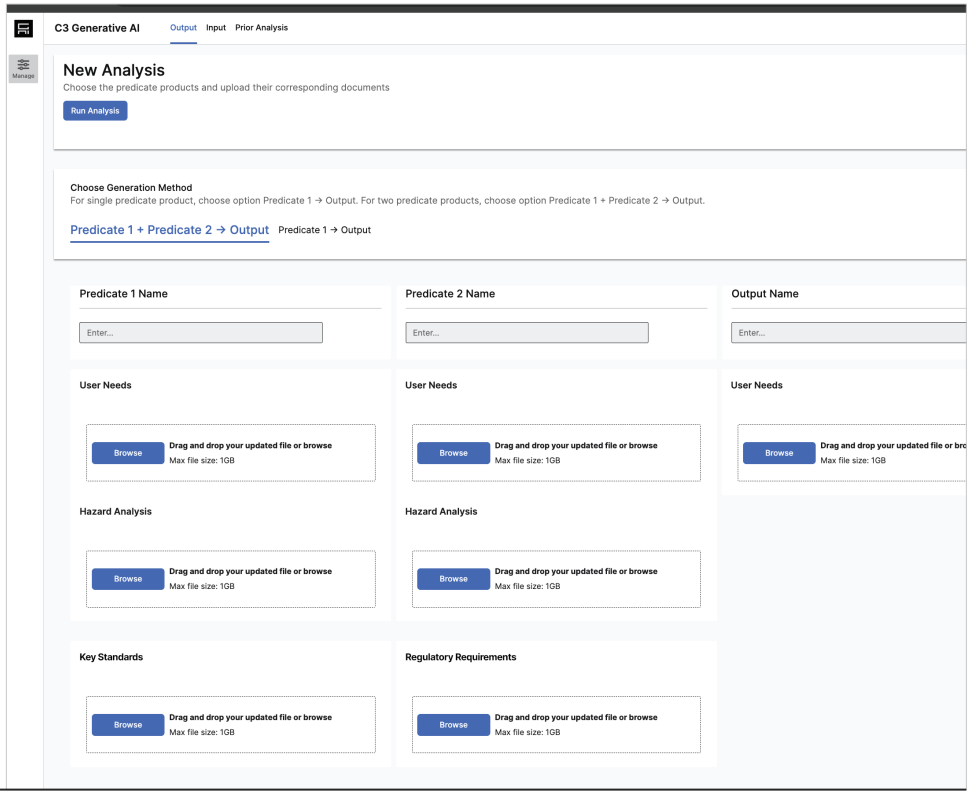
In the next development phase, C3 AI will deploy additional applications for other documentation tasks across the R&D documentation value chain and across departments or divisions. This will help the company reduce 500,000+ hours (~10% of total time) and significant portion of the nine-figure spend on R&D documentation.

Solution Architecture

C3 Generative AI

Enterprise Data

- Historical risk and R&D documentation
- Predicate products
- Protocols and compliance guidelines
- User feedback and complaints



Benefits

By using the C3 AI Generative AI for R&D Documentation Acceleration application, the leading medical device company is able to:

Reduce

99% of the time to create hazard analysis documents from weeks to minutes.

Improve

QA engineer adoption of the application with intuitive user interface, easy workflow, and output relevance checking for effective reviews.

Achieve

up to 90% accuracy for the automatically created hazard analysis by C3 Generative AI for Documentation Acceleration.

Ensure

the automatically generated hazard analysis documents comply with the company's policies and governance frameworks via security and compliance features.

Proven Results in Weeks

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