Docuvera™

AI + Structured Content

A new era of pharmaceutical documentation

Executive summary

The pharmaceutical industry is witnessing a significant transformation in its documentation processes. Thanks to the convergence of AI and structured content technologies, we're cleverly crafting initial document drafts by combining human-reviewed components with AI-generated content. Moreover, AI can quickly translate content into multiple languages, create lay summaries that make complex information accessible to a broader audience, and automate the laborious processes of tagging content with metadata or extracting key terms for improved findability. AI also assists with ensuring content is complete through integrity checks and by creating new ways to distribute content, such as chatbots.

With AI assuming the heavy lifting of manual tasks, valuable human resources are freed for more strategic initiatives.

But AI isn't working alone. Structured content solutions like Docuvera provide the controls and standardization mandatory for the highly regulated pharmaceutical world by offering robust audit trails and compliance measures essential for maintaining trust and transparency throughout the documentation process.

This powerful combination enables pharmaceutical companies to reuse trusted content efficiently, building a system that distinguishes between machine-generated and human-reviewed material. In an industry where regulatory compliance is table stakes, Docuvera is proving to be the perfect complement to AI, addressing the implementation challenges of integrating new technologies.

The result? A more efficient documentation process that produces higher-quality, standardized documents that meet the pharmaceutical industry's stringent requirements.

AI + structured content:
Pharmaceutical documentation's perfect pair

AI and structured content are proving to be the dynamic duo of pharmaceutical documentation. AI tackles time-consuming manual tasks that have long bottlenecked the documentation process. Docuvera provides the scaffolding for structured and standardized content development, including its ability to clearly show the difference between machine-generated and human-approved content while maintaining robust traceability.

AI is the new workhorse of process

AI is revolutionizing the documentation process by taking on repetitive tasks that have traditionally consumed so much time. This shift allows pharmaceutical professionals to redirect their energy towards more strategic, value-added activities.

First drafts, crafted with AI precision

AI technologies, including the impressive Generative AI (GenAI), can now produce initial document drafts that combine the best of both worlds: human-reviewed content components and AI-generated elements. A hybrid approach ensures that drafts are accurate while streamlining the downstream review processes by reusing previously approved content.

> ***With Docuvera, it's like having a highly skilled assistant who can quickly pull together a draft by analyzing existing human-reviewed components, reusing relevant information, and tapping into GenAI to create new content only when existing components do not address the need.***
>
> **— Steve Owens** | Chief Product Officer

Breaking down language barriers

With the capability to automatically transform content into different forms, AI is a linguistic powerhouse. It translates documents into multiple languages, ensuring crucial information is accessible globally and compliant with local regulations. But it doesn't stop there. AI also generates lay summaries for non-specialist audiences and adjusts verb tenses to suit different contexts. This versatility is particularly valuable in the pharmaceutical industry, where documentation needs to be understood by a diverse range of stakeholders, from regulatory authorities to healthcare professionals and patients.

Metadata tagging = automatic attention to detail

Accurate document and component content metadata is critical as the pharmaceutical industry transitions from a document-centric to a data-centric model. AI can automatically tag properties and values to documents and components. As more documents and content components become enhanced with metadata, new opportunities emerge, like automating the process of data submission to regulatory authorities and leveraging content components for targeted patient information. By eliminating the manual tagging process, AI reduces the risk of human error and improves the efficiency of data management processes.

AI as a quality control expert

AI, stepping into the tireless quality control expert role, can perform automated checks on documents to ensure accuracy and completeness. It cross-references data, detects inconsistencies, and flags missing information. An automated review process ensures that all documentation meets the required standards before subsequent human reviews. AI also highlights potential issues for review workflows, providing an additional layer of quality assurance — invaluable in an industry where accuracy and completeness are non-negotiable for regulatory compliance and patient safety.

Repurposing content for the digital age

AI breathes new life into existing content by repurposing it for various channels, such as chatbots, mobile applications, and additional export formats. By transforming and adapting content to suit different platforms, AI ensures that information is accessible to a broader audience. For instance, it's converting technical documents into conversational formats for chatbots, making it easier for users to obtain information. This flexibility enhances the reach and utility of pharmaceutical documentation, ensuring that it meets the needs of diverse stakeholders in our increasingly digital world.

Docuvera delivers structure and compliance for content management

While AI automates manual tasks, structured content provides the essential guardrails and compliance measures needed in the pharmaceutical industry. It offers a systematic approach to content development, ensuring consistency and standardization across all documents. Docuvera also supports compliance with regulatory requirements by providing robust validation and audit trails.

Unlock the power of content reuse

Docuvera enables the reuse of trusted, human-reviewed content across different documents and projects. Organizations can leverage AI to easily retrieve and reuse human-reviewed content instead of generating new content by storing content components in reference documents or governed projects. This approach saves time through streamlined review processes (humans have already reviewed reused components) and ensures consistency and accuracy across all documents. Reusing validated content reduces the risk of errors and discrepancies, enhancing the overall quality of documentation.

Trust built through transparency

IIn the world of pharmaceutical documentation, trust is paramount. Docuvera builds this trust through its robust governance and audit trail features that meticulously track all changes made to documents, recording who made the changes and when. Transparency ensures accountability and allows for thorough audits of the documentation process. Docuvera's governance policies and audit trails are essential for maintaining compliance with regulatory requirements and building confidence in the integrity of AI-generated content. They provide a clear record of the content's development, review, and approval process, ensuring all stakeholders can trust the information.

Keeping AI and human contributions clear

One of Docuvera's key strengths is its ability to differentiate between machine-generated and human-reviewed content — a crucial distinction for maintaining transparency and trust in the documentation process. Stakeholders can quickly identify the sources of information and understand the level of human oversight involved; this is beneficial during review processes, allowing reviewers to focus their energies on GenAI content versus human-reviewed, reused components. By marking AI-generated content and tracking subsequent human reviews and approvals, organizations can ensure that all content is accurate, reliable, and compliant with industry regulations.

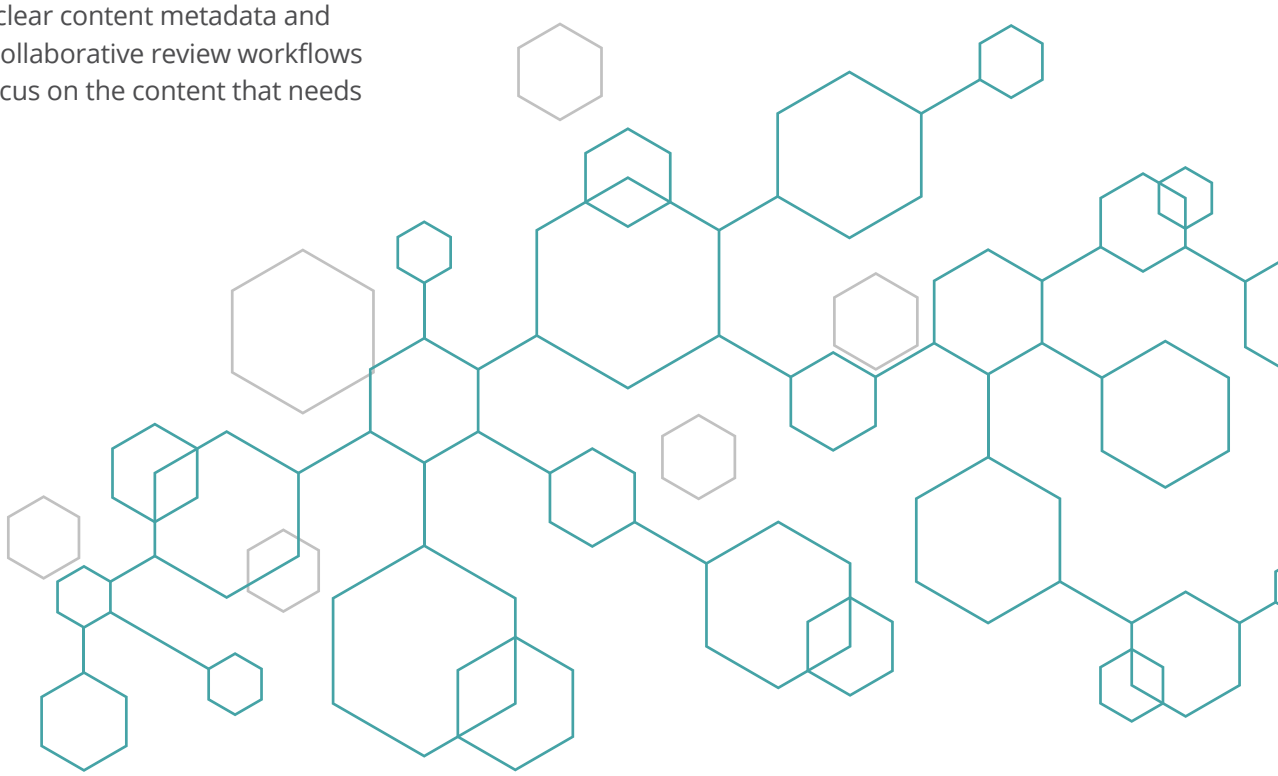
Review and approval, streamlined

Docuvera supports comprehensive review and approval workflows, ensuring that all documents undergo thorough vetting before finalization. Workflows include multiple review, feedback, and approval stages involving AI and human reviewers. AI content integrity checks can automate the process of identifying missing or inaccurate information, while clear content metadata and audit trails during collaborative review workflows allow humans to focus on the content that needs the most oversight.

Docuvera also offers robust versioning capabilities, tracking all changes and maintaining a clear record of component and document revisions. This ensures that organizations can easily manage and retrieve previous versions of documents, facilitating ongoing quality control and compliance. Robust review and versioning processes are essential for maintaining the integrity and accuracy of pharmaceutical documentation.

Continuous improvement through learning

Docuvera uses component content to improve results generated from large language models (LLMs). Using validated content components through techniques like RAG (Retrieval Augmented Generation), these systems provide LLMs with high-quality data, enhancing their accuracy and performance. Component content also allows for the incremental improvement of AI models, incorporating new information and best practices as they become available. This approach ensures that AI-generated content remains reliable and aligned with industry standards.



Docuvera's AI + structured content technology approach

Docuvera has been hard at work developing cutting-edge technologies that fully embrace AI capabilities within its structured content management platform.

Retrieval-Augmented Generation and Reuse: The intelligent way to create content

Docuvera leverages Retrieval-Augmented Generation (RAG) and Retrieval-Augmented Reuse (RARe) techniques. These smart approaches combine information retrieval with generative AI to produce more accurate and relevant content.

Target clustering is a vital part of this process, ensuring that when AI generates content, it's coherent and contextually appropriate. It's like having a super-organized filing system that groups related information together.

Serving as a knowledgeable assistant who knows precisely which pre-approved information to use in each situation, RARe goes a step further. By clustering approved, human-reviewed content components, Docuvera then automatically selects the most relevant validated content and inserts it into documents based on the context.

The system also employs features, including:

- **Hybrid search** combines traditional keyword-based and advanced semantic search techniques. This allows the system to understand the context and meaning behind search queries, providing more accurate and relevant results.
- **Automatic prompt engineering** designs and refines the prompts to guide the AI in reusing or generating content. Prompts can be tailored to specific document types, such as clinical trial reports or patient information leaflets to ensure AI produces content that meets required standards and formats.
- **Auto-propagation** further enhances efficiency by automatically creating documents based on the optimal components identified in the RAG and RARe processes, reducing the manual searching/selecting activities involved in document creation.

NLPs make sense of complex information

Natural Language Processing (NLP) is used for topic classification, which involves categorizing components and documents based on their content and subject matter. This makes organizing and retrieving documents easier and ensures the correct information is accessible when needed.

NLP algorithms can analyze components and documents, tagging them with specific codes to enable new data submissions to regulatory authorities. It can also automatically extract critical terms and phrases from documents, helping to identify the main topics and themes — particularly useful when dealing with large datasets, where manual classification would be time-consuming and prone to errors.

Another handy feature enabled by NLP is content summarization, which pare down lengthy documents, providing concise overviews of the main points. This is valuable for stakeholders who need to quickly grasp the essential information in a document without reading the entire content.

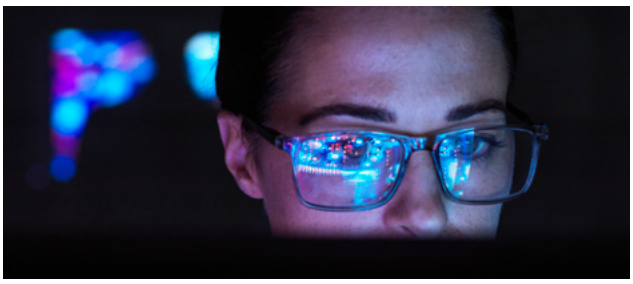
Generative AI transforms content in 3 powerful ways

Generative AI (GenAI) creates and transforms content, ensuring it meets specific requirements and formats. In pharmaceutical documentation, GenAI enables various content transformations, enhancing the efficiency and accuracy of the documentation process, including:

- **Content summarization:**
  When GenAI generates lay summaries for non-specialist audiences, complex scientific information becomes more accessible — important for patient information leaflets and public health communications.
- **Language translation:**
  GenAI can translate documents into multiple languages, ensuring they are accessible to a global audience. This capability is crucial in the pharmaceutical industry, where documents must comply with regulatory requirements in different countries. While GenAI is proving valuable for use cases like back-translation today, as these engines improve, GenAI will increasingly assume more primary translation tasks for medical information.
- **Content adaptation:**
  GenAI can adjust the tone, style, and format of content to suit different audiences and contexts. For example, it can transform technical documents into more conversational formats for chatbots or mobile applications.

Seamless integration brings it all together

To ensure smooth operation, Docuvera integrates AI capabilities into existing systems and workflows using an Enterprise Service Bus (ESB) and Application Programming Interfaces (APIs). These technologies ensure seamless communication between different systems, enhancing the overall efficiency and functionality of the pharmaceutical documentation process.



The Enterprise Service Bus acts like a central nervous system, facilitating communication and integration between software applications. In the context of AI integration, it connects various AI tools and systems with the Docuvera platform, ensuring that they work together seamlessly.

APIs, on the other hand, perform as universal translators. They enable the integration of AI capabilities into existing documentation systems, allowing for real-time data exchange and automation. For example, APIs can integrate AI-powered content generation tools with document management systems, ensuring that many manual processes can be automated within the documentation lifecycle.

Our integration approach facilitates the smooth flow of data from various AI tools to the Docuvera platform and other elements of an enterprise's ecosystem (e.g., document management systems, etc.). It allows an enterprise to leverage existing systems critical in its overall workflows while layering new AI capabilities on a governance platform that provides essential layers of governance and compliance.

Why can't I just use AI on its own?

Docuvera addresses several critical areas necessary to responsibly integrate AI into a scalable, regulated pharmaceutical operation.

1. Migration is a complicated process

Migrating to an AI-integrated system is like moving to a new house; you can't just throw everything into boxes and hope for the best. In the highly regulated pharmaceutical industry, this process requires meticulous planning and execution. When transferring vast amounts of data from legacy systems to modern platforms — no critical information can get lost in the move.

Enter componentization. Documents are broken down into reusable content components, which can be tagged, organized, and managed more effectively. Just like unpacking boxes and organizing everything neatly in your new home.

A structured content solution lays the groundwork. Docuvera preserves data's integrity and sets the stage for more efficient document management and content creation processes. Plus, well-organized components can provide necessary high-quality data to leverage in various AI models, making them smarter and more effective over time.

2. Reuse and content change propagation needs rules

Consistency is key in pharmaceutical documentation. AI systems need to support the reuse of existing, validated content. Reusing content components that have undergone rigorous review ensures document consistency and accuracy.

Stay in sync when content updates. When changes are made to a content component, they need to effectively propagate through all documents that use that component. Docuvera ensures all related documents stay up-to-date and compliant with the latest content versions.

3. Versioning, change orders, and audit trails don't track themselves

For the pharmaceutical industry, it's essential to know who did what, and when. Having the latest version of a document is not enough; you need to be able to trace its entire history. AI systems must support robust version control, allowing organizations to maintain a clear history of all component and document revisions.

Keep track of everything. Comprehensive audit trails aren't just about ticking boxes; they enable organizations to demonstrate compliance during inspections and audits, proving that all documentation processes meet regulatory standards. Change orders and audit trails are the breadcrumbs that track who made changes, when they were made, and why. This level of detail provides the transparency and accountability critical in regulatory environments. The Docuvera solution is like having a time machine for your documents: you can see precisely how they've evolved.

4. Review and approval workflows need control

Even with AI in the mix, human oversight remains crucial. AI-augmented content must include structured review and approval workflows to ensure that all documents undergo thorough vetting before being finalized.

Ensure quality at every step. Review and approval workflows typically involve multiple stages of review by different stakeholders, including subject matter experts and regulatory compliance officers. While AI streamlines workflows by automating specific tasks, such as routing documents to the appropriate reviewers and tracking their progress, Docuvera taps into essential human expertise to verify the accuracy and completeness of AI-generated content.

5. Exporting and submissions are error-prone without guardrails

Creating great documentation is not enough. You also need to be able to deliver it in the right format to the right people.

Regulatory environments require documentation to be submitted in specific formats — through designated channels. To meet these requirements, AI systems must support the export of documents in various formats, such as Word, PDF, XML, or industry-specific standards. Additionally, AI tools should facilitate the submission process by automatically packaging and transmitting documents to regulatory authorities.

Cross the finish line. Docuvera's export and submission capabilities reduce the risk of errors during submission and ensure that all documents comply with regulatory guidelines. It's like having a personal assistant who prepares your documents and ensures they're delivered correctly and on time.

6. Reporting requires visibility into the entire documentation process

Regular reporting to authorities and other stakeholders is par for the course. AI systems need to step up to this challenge by incorporating the generation of detailed reports that provide insights into the documentation process.

Help everyone stay informed. With Docuvera, reports cover metrics on document creation, review, and approval timelines. They can also highlight discrepancies or compliance issues, enabling organizations to address them proactively. It's like having a dashboard that gives you a bird's-eye view of your entire documentation process.

7. Different users require different permissions

In regulated industries, controlling who can access and modify documentation is crucial. AI systems must incorporate robust permissions management to ensure only authorized personnel can change documents. This involves setting up role-based access controls, where different users have varying levels of access based on their roles and responsibilities.

Keep things under lock and key. The tight control available in the Docuvera solution helps prevent unauthorized modifications, ensuring that all changes are traceable and compliant with regulatory standards. By controlling access, organizations can protect sensitive information and maintain the integrity of their documentation processes.

Driving change for pharmaceutical documentation

The synergies between AI and Docuvera are ushering in a new era, transforming how the industry approaches its documentation processes by automating tasks, ensuring accuracy, and enabling smart content reuse. This union is building trust, boosting efficiency, and reinforcing regulatory compliance — all critical factors in the pharmaceutical world.

As our industry continues to evolve rapidly, the combination of AI and Docuvera will be essential for maintaining high-quality, standardized, and data-driven documentation.

Now, It's not just about keeping up with changes, but driving them. By embracing AI and Docuvera, pharmaceutical companies can position themselves at the forefront of innovation. In this dynamic landscape, we're helping organizations navigate the complex waters of pharmaceutical documentation with confidence and precision.

8. Ecosystem integrations are essential in life sciences

AI systems in regulatory environments need to be team players that can integrate seamlessly with existing IT ecosystems, including document management systems, regulatory submission portals, and other enterprise applications.

Play well with others. Docuvera's integration capabilities ensure data flows smoothly between different systems, enhancing overall efficiency and accuracy. APIs and other integration tools facilitate this connectivity, allowing AI to access and utilize data from various sources. Effective ecosystem integration is essential for creating a cohesive documentation process that leverages the strengths of different technologies and systems.

9. AI (on its own) still needs validation

Before AI systems can be released into regulatory environments, they must undergo rigorous validation to ensure they meet all regulatory requirements. This process involves comprehensive testing to verify AI's accuracy, reliability, and compliance, as well as testing for data integrity, performance, and security, among other factors.

Proving it works. Regulatory authorities often require detailed validation documentation as part of the approval process. Docuvera ensures that AI systems are adequately validated and provides confidence that they will perform as expected and comply with all relevant regulations, minimizing the risk of non-compliance and associated penalties.

There's a lot of buzz around AI in the pharmaceutical space, and for good reason. It's set to revolutionize documentation processes in the sector. However, it's essential to recognize that AI isn't a magic wand that can solve all problems independently.

Ready to see for yourself how Docuvera is transforming documentation?

Reach out today for a personalized demo

Docuvera is an integrated, cloud-based structured component authoring (SCA) solution that allows organizations to create, share, and manage regulatory documents more efficiently. Developed by ASC, a world leader in component-based authoring solutions, Docuvera was explicitly designed to focus on the needs of the life sciences industry. By combining familiar interfaces with innovative technology solutions and databases, Docuvera brings consistency and greater compliance to the life sciences documentation process. Visit docuvera.com to learn more.

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