

From documents to data

5 ways medical device companies can go to market faster with structured content, automation and AI



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Executive summary

The medical device industry is facing unprecedented challenges. The growing elderly population is increasing the demand for medical devices worldwide. And stringent regulations – paired with relatively low investment in digital technologies compared to other industries – are making it harder for OEMs to bring compliant devices to market at speed.

To overcome those challenges, OEMs must identify new tools and processes that can help them lower costs and bring better, safer devices to market, faster.

The first step in that journey is letting go of paper-based quality management systems. Once in the digital world, MedTech organizations can look at how content creation and management processes can be made more efficient with the help of specialized approaches like the one enabled by structured content.

Content reuse and automation are well-known concepts in the medical writing world, but legacy decisions in a very change-adverse industry mean that many writers still aren't getting the full benefit from them.

By creating content only once and pushing it through an automated review and publishing workflow, every stakeholder in the documentation creation process is empowered to finish their job faster. And when everyone finishes their job faster, devices can be brought to market faster too.

With that digital foundation laid, the final ingredient can be added – Artificial Intelligence (AI).

AI increases efficiency and accelerates processes even further when applied to machine-readable content. With AI co-pilots handling routine parsing tasks, writers are empowered to focus on data interpretation and complex duties that demand their human expertise.

This paper explores five ways medical device companies can overcome the challenges associated with complex, time-consuming regulatory submission processes, and ensure seamless product launches, all while preparing themselves for a paperless, fully digitized future.

We will show you how structured content, automation and AI can help you:

- ◆ Enable agile authoring
- ◆ Automate review and approval workflows
- ◆ Reduce translation times and costs
- ◆ Create documentation that is consistent and compliant
- ◆ Quickly update and publish documentation for any output



Launching safe and effective medical devices

Before a medical device can be brought to market, it must be supported by multilingual, accurate and compliant documentation which is complex.

That documentation is used by regulators to approve and understand devices, by customers and practitioners to support their use of medical devices, and by organizations themselves as they go to market with their new products. Without it, medical devices simply can't be brought to market.

However, the processes and systems used to create that documentation are often cumbersome and become a bottleneck, holding up device launches. As recently as 2020, more than 50% of MedTech "organizations" still use paper-based or ad hoc systems¹, leaving teams with no insight into the quality of their content or its readiness for publishing.

Fortunately, several key technologies have emerged to help. Structured content, automation, content management tools and AI all have a role to play in the acceleration and improvement of medical device documentation processes.

Now, let's explore exactly how medical device OEMs can take advantage of the new tools, capabilities and practices available, and apply them to launch safe, compliant products faster and more efficiently than their competitors.

A paradigm shift for content management

From design prototyping to localized press releases and launch announcements – medical device information must always be accurate and consistent. No matter the channel or output type. There is zero tolerance for errors.

All that means paper-based approaches are no longer fit for purpose. It's time to optimize content development processes.

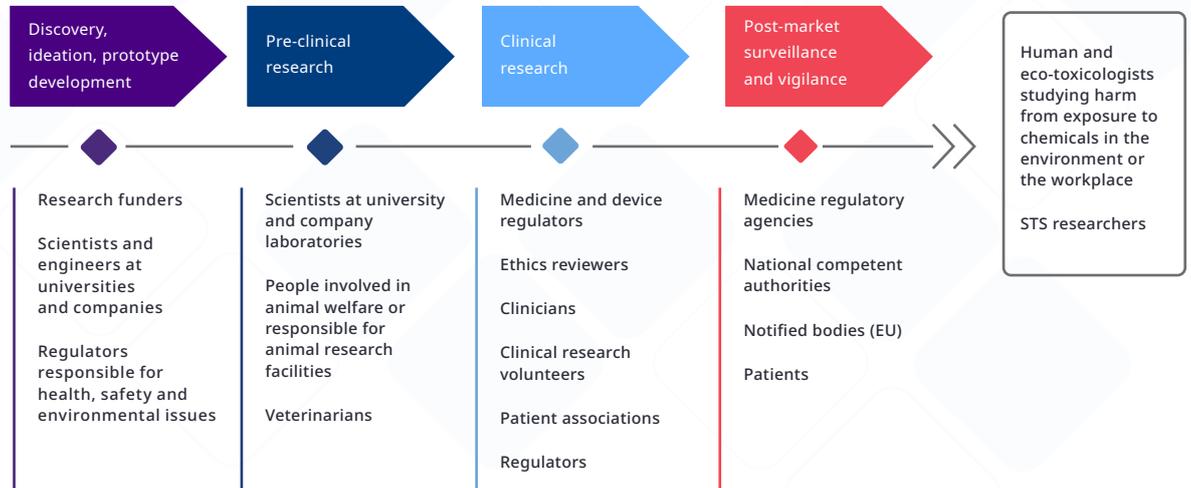
Paper-based systems won't cut it

In medical device documentation, there's a wide variety of stakeholders, ranging from medical writers to regulatory bodies to medical personnel and patients. They all have different expectations and needs, making the process too complex to be managed sustainably in the traditional way.



¹ Document Control for Medical Device Companies: The Ultimate Guide (greenlight.guru)

Medical device stakeholders



For example, when dealing with complex content during the design and development phase, updates and changes must be made in the Design History File (DHF), a set of documents defined by relationships between the different content files it contains, to prove the product is safe. Organizations need to maintain traceability by creating a traceability matrix that shows the relationships between content pieces at every stage of the production and publishing lifecycle, including user needs and design inputs, outputs, verification and validation.

That's a complex process. Imagine how it looks when documents and information are managed in a paper-based format. Without a clear or consistent view of crucial information, medical writing teams make mistakes that lead to delays in product launches, face rejections from regulatory bodies, or can even create the premise of possible lawsuits by presenting inaccurate content in commercial communications.

Is a digital, document-based approach enough?

So, paper processes aren't viable. But is it enough to manually manage information across digital documents and work with word-processing files and PDFs?

Let's take the previous example of the DHF. When a design specification detail needs to change in the DHF, it must be updated across all files that contain that piece of information. This means manually copying and pasting information from one file to another – a procedure that is very error-prone.

When using word processors to create, review, approve, publish, maintain and archive medical-related content, there are no clear change tracking mechanisms and it's not always easy to know what the latest updated version of a document is.

To solve these problems, a broader, more fundamental shift in documentation processes is required.



From documents to data

OEMs need to revisit the entire notion of working with documents. The success and speed of documentation processes depends on medical writers' ability to access and interpret reliable data and extract relevant points for the documents they create. So, the first logical step in a MedTech organization's evolution is to start treating documents as data.

There are three key capabilities that can support and enable that evolution: Structured content management systems, automation and AI.

Structured content

Structured content management systems, also known as Component Content Management Systems (CCMS), are tools for creating and managing componentized content in a data-driven way. These enable granular control over who made what changes when, and where, to any specific content chunk, rather than using monolithic documents. With a structured content management tool, document owners and medical writers gain a comprehensive overview of the entire set of content components used across documents, product versions and language variants.

When adopting a CCMS, instead of working with documents as the smallest unit of measure, the smallest unit of measurement is as granular as the medical writing team defines it to be. It can be a paragraph, image, video, sentence or the name of a product – and it's defined as the single source of truth. This means a piece of content is created and approved only once and can then be reused wherever necessary without going through the authoring, reviewing and approval cycles all over again: a concept known as COPE: Create Once Publish Everywhere.

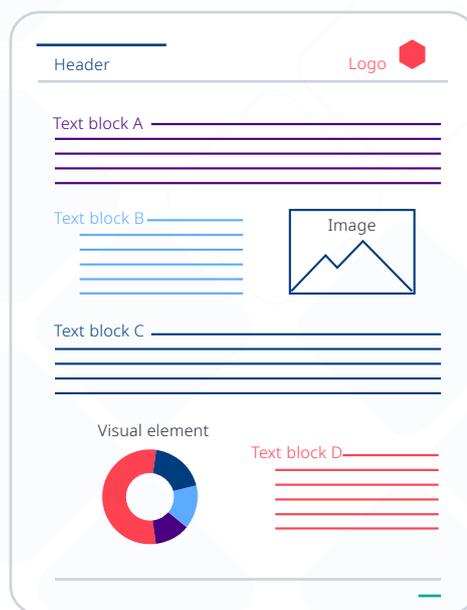


Figure 1: Content components assembled into a document

Content automation

A CCMS is based on automation. The content components in the documentation are not placed there by copying and pasting them, but by retrieving them from the database where they are stored as the single version or the single source of truth.

But automation can be applied to all aspects of content creation, not just authoring. Review and approval cycles can be transformed into automated content workflows so that after each revision, content is automatically directed to the approver to be accepted, revised or sent back with comments. The publishing phase is completely automated as well, as the publication is created by the tool by merging all content components in one file with a pre-defined structure, style and design.

Whenever a small detail needs to change in the documentation, the approval of the new content goes through complex change control processes as defined by local requirements, such as the 21 CFR Part 82 in the US. With the help of a CCMS and automated change control workflows, those processes happen by default – giving medical writers more time to focus on the intrinsic quality of content and correct data interpretation.

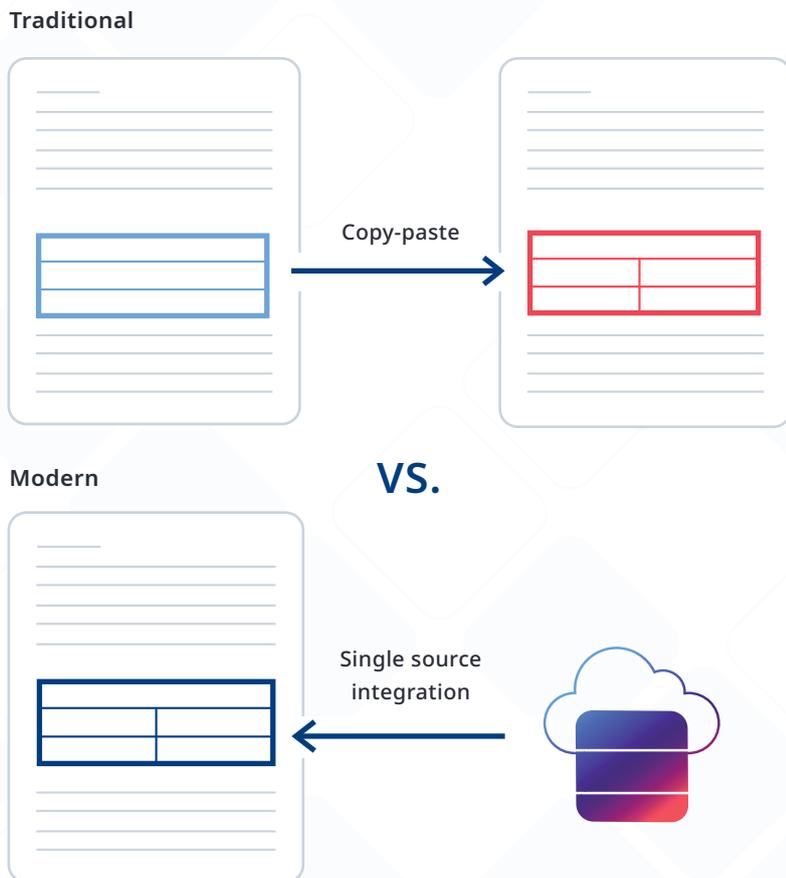


Figure 2: Copy-paste vs. content automation

From documents to data

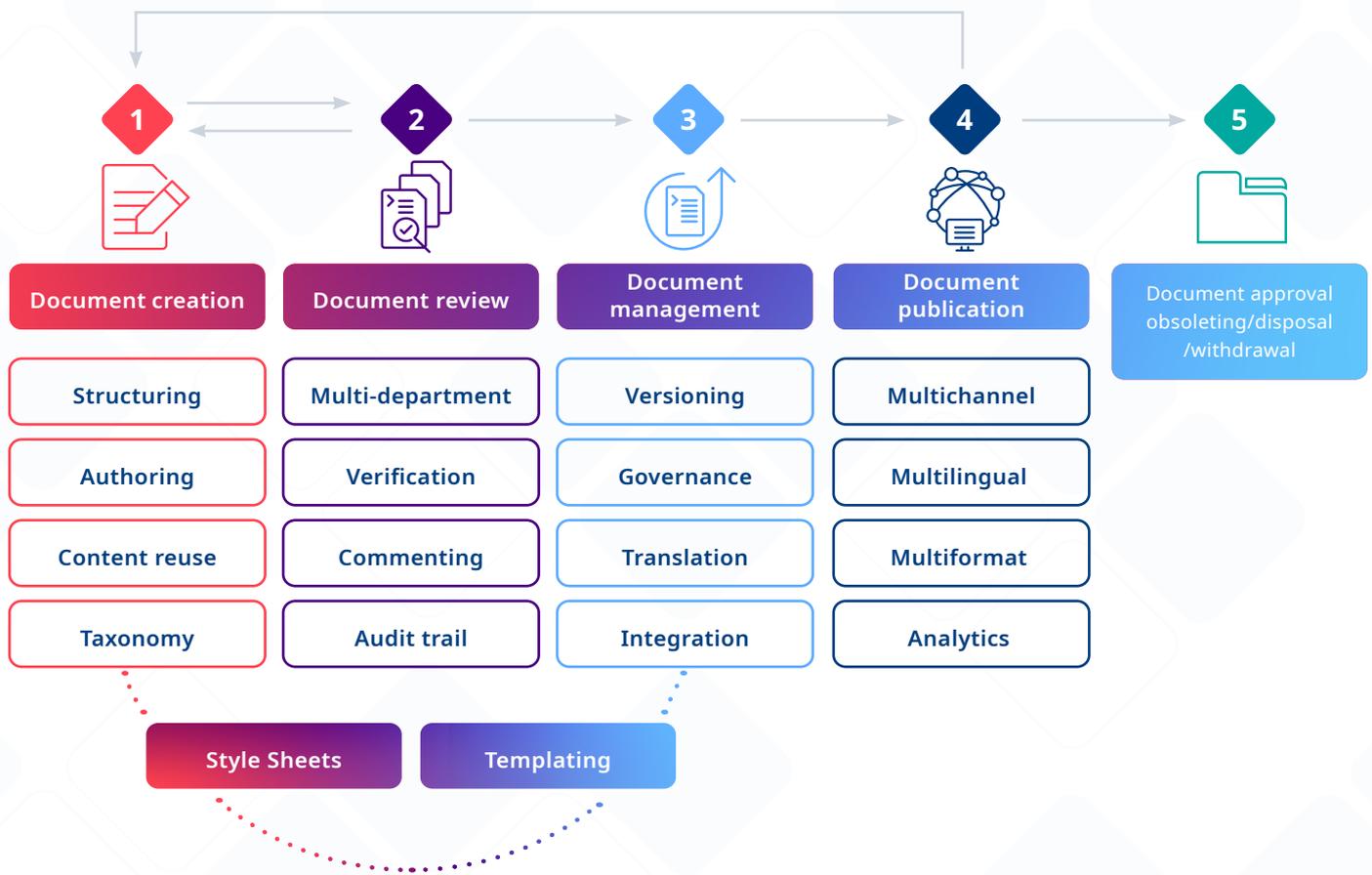


Figure 3: The lifecycle of a medical device document with structured content

Medical documentation must adhere to strict rules such as:

- ◆ The EU MDR (Medical Device Regulation) and IVDR (In Vitro Diagnostics Regulation)
- ◆ **FDA regulatory requirements**, like MDR (Medical Device Reporting)
- ◆ Premarket notification standards, like ISO 13485

Content automation helps medical writers and medical device organizations create content authoring, review, approval and publishing workflows that are in accordance with these rules, which means:

- ◆ Medical writers build documentation that's traceable, high-quality and satisfies regulatory requirements
- ◆ Medical OEMs can prove their content management processes are consistent, reproducible and repeatable

Metadata and semantic AI

The final piece of the content and data management puzzle is ensuring that information is easy to find for all of the stakeholders that need to access it. This can be achieved by implementing componentized content that is metadata-tagged using industry taxonomies. This way, content is semantically enriched while building connections between content components. Content has a distinct meaning and purpose identified by meta-tags and is much easier to find by medical writers, in a CCMS or by patients, in a product portal. Information findability can increase even further with the help of machine learning algorithms.

Semantic AI algorithms can be added to a CCMS to scan content and understand what it means. Coupled with the relationship between different content elements provided by meta-tags, you now have a structured content management tool where medical writers can identify content faster and reuse it wherever needed.

As opposed to the traditional document-centric approach, the structured content paradigm transforms content from a single compact unit of information that needs frackting to make use of it, to a set of modular data components. Those components are format-free and ready to be integrated into clinical investigation plans, regulatory submissions templates or commercial websites as required.



Documents that are enriched with structured data will become more mainstream to help with high-volume transactional document processing."

Cheryl McKinnon, Principal Analyst,
Forrester²

² *The Future Of Documents: Content Creation Is Ripe For Its Own Digital Disruption (forrester.com)*

3 stages from documents to data



Structured content authoring

By authoring, reviewing and approving components, medical writers are more efficient and collaborative authoring is improved.



Document automation

Medical device documentation is automatically produced – built from reused components and templates that are automatically populated with data. Output is still a traditional document.



Omnichannel publishing

Medical device OEMs can publish more than just documents. They can integrate data sets directly into knowledge portals, patient-facing outputs or medical device interfaces.

1. COLLABORATION

2. AUTOMATION

3. DATA PUBLISHING

Figure 4: The 3-stage process of evolving from documents to data



Adopting generative AI

There's no doubt that generative AI will change content creation for medical writers – but not quite in the way some fear. Generative AI algorithms can perform two types of tasks for them:

- A. Writing content from scratch and unassisted
- B. Assisting medical writers in creating content

Medical device OEMs and regulators understand the importance of having humans at the centre of the process. For 100% accuracy, design and development plans, clinical evaluation reports and regulatory submissions need human input.

However, it's a different story when it comes to using generative AI to support content generation. In this case, AI becomes a co-pilot that helps medical writers achieve their targets faster by:

- ◆ Suggesting rephrased versions of sentences or paragraphs with a poor readability score
- ◆ Detecting incorrect usage of terms or product names and proposing alternatives
- ◆ Acting as a virtual assistant for writers and helping them find information faster



AI applications used for drafting, compiling, translating, or reviewing medicinal product information documents are expected to be used under close human supervision. Given that generative language models are prone to include plausible but erroneous output, quality review mechanisms need to be in place to ensure that all model-generated text is both factually and syntactically correct [...].”

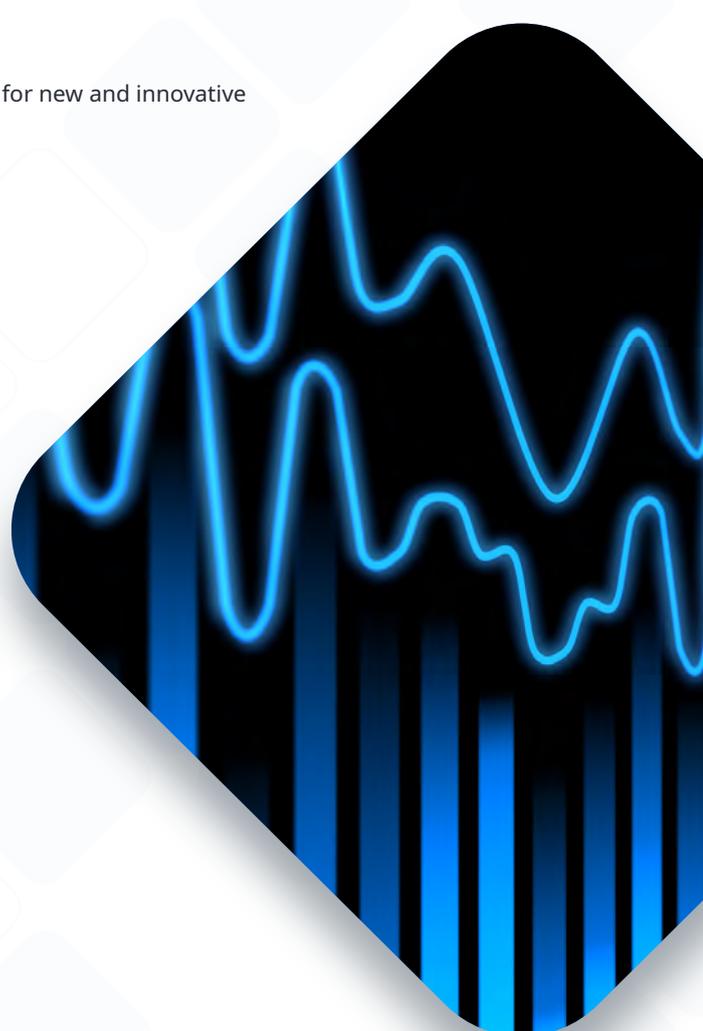
European Medicines Agency³

³ Reflection paper on the use of artificial intelligence (AI) in the medicinal product lifecycle | European Medicines Agency

Although generative AI is not part of medical writers' everyday realities yet, this technology will be adopted faster than we think and there will be only one winner – enterprises working with structured content that is easily read and understood by both humans and machines.

Benefits of structured content, automation and AI for medical writers

- ◆ Increased efficiency
- ◆ Improved output consistency
- ◆ Higher document quality in any language
- ◆ Exponentially reduced risk of errors
- ◆ More time to focus on data interpretation and message
- ◆ Increased content findability
- ◆ Intuitive tagging suggestions and taxonomy browsing
- ◆ Search suggestion capabilities
- ◆ Creating and working with content that is ready for new and innovative technology adoption





5 ways structured content, automation and AI help medical OEMs launch products faster

The MedTech industry tends to lag behind many others when it comes to adopting new technologies. That's largely because its core goal is to deliver safe and effective products to market, which long-established legacy processes and tools can do – eventually.

But, faced with rising demand and rapid change, many organizations are embracing digitalization as a way of accelerating their content creation and publishing processes. 69%⁴ of MedTech company leaders say that the transformation of functions using digital and information technologies will remain a top priority over the next five years.

The main purpose of digital investments is to reduce costs as well as to improve R&D and gain insights into business strategy execution

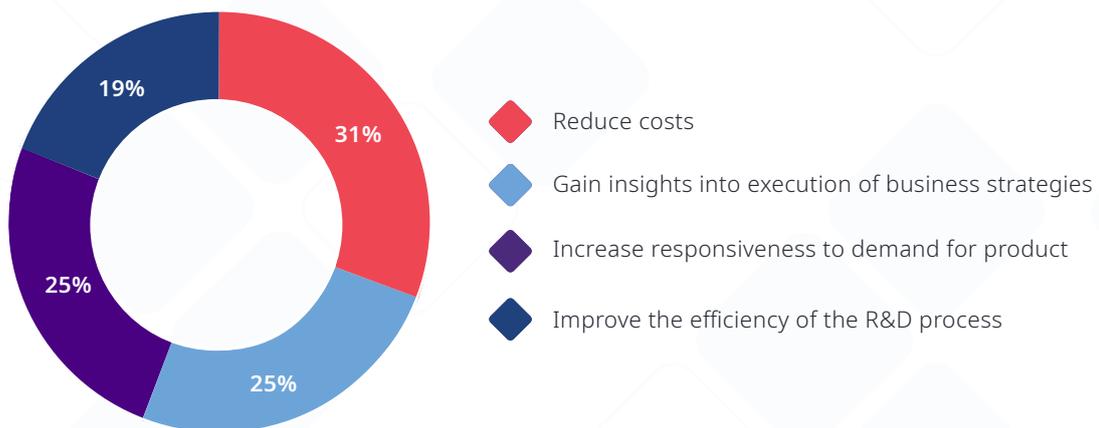


Figure 5: What teams hope to gain by investing in digitization⁵

By investing in a structured content management solution that is enhanced with AI capabilities, MedTech OEMs can boost productivity, increase speed to market and outpace their competition. With structured content, organizations can take a more agile path to creating content and transform their operations in five key ways:

^{4,5} Medtech industry challenges and opportunities | Deloitte Insights



Agile authoring

Compared to a traditional authoring environment, structured content and CCMS tools enable authors, reviewers and SMEs to adopt an agile way of working. As opposed to being created sequentially, paragraph by paragraph, content elements are created independently and in parallel.

Once all components have been approved, they are collated into the final form of the publication. Whenever a change needs to be made, updated versions can be published far faster, as only the components that require modification need to be updated.

Those components can then easily be flowed into document structures, defined by document owners. Within those structures, owners can define document sections and clear content rules for what type of content – images, text, tables – can be used in what part of their documentation. The structure is set from the beginning, and it cannot be modified by authors and reviewers – eliminating the possibility of unapproved changes or unintended editing errors.

Each content module only needs to be created and approved once. After that, it becomes the single source of truth for its subject matter and purpose. Modules can be widely and immediately reused, reducing duplicated writing effort, and eliminating repetitive creation, editing and approval tasks.

But it doesn't just make processes faster. That approach also ensures all content is highly consistent, and that the same terms and phrasing are used when talking about the same subject. That consistency improves reader experiences, and helps ensure that all documents are clearly understood by regulatory authorities – increasing approval rates.

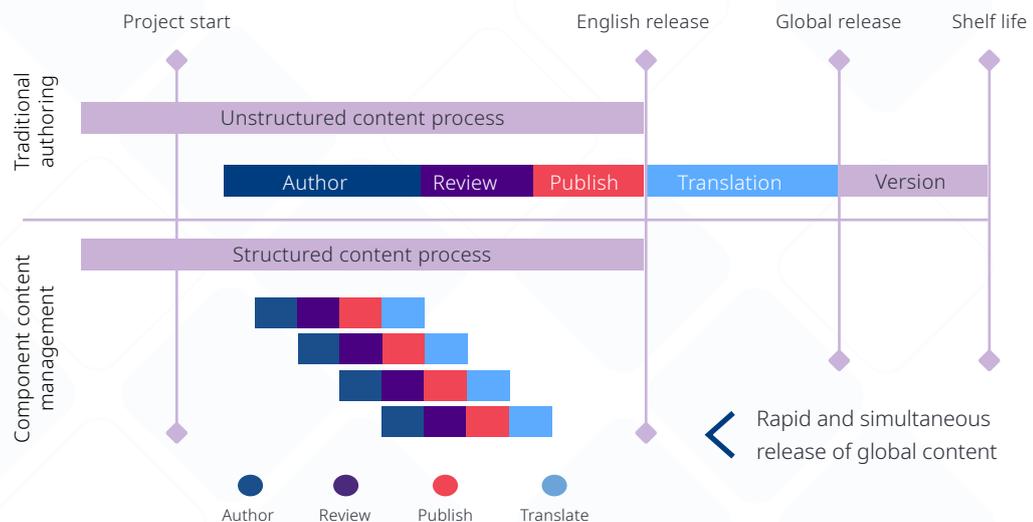


Figure 6: Simultaneous content creation as enabled by structured content.



Automated review and approval workflows

One of the most important rules that needs to be followed when creating medical device documentation is maintaining traceability. With componentized content, medical writers can quickly trace what content chunk has been used where, and how many times, across documents. Component authoring also enables accurate change tracking, allowing document owners to see who did what, when and where, and quickly prepare audit trails.

Using a centralized CCMS rather than several different systems to review and approve content, stakeholders will also find it much easier to collaborate and share ideas. All content is stored in the same platform, and is accessible to everyone in the same place, which ensures every stakeholder stays on the same page and works from the same document versions at any given time.

Reviews and comments are held in the same platform too, so editors, reviewers and SMEs don't have to worry about misplacing or losing them. There is no need for PDFs with annotations or post-its left on printed documents that must be reviewed. All comments and revisions are stored in a single place where the writer can easily manage them by asking further questions, leaving comments or implementing the suggested changes.





Reduced translation times and costs for multilingual content

Medical devices are often marketed in several countries with different official languages. Medical documentation needs to be translated clearly, so that it can be properly understood by every user and regulatory body that needs it, in every country.

Translation processes are notoriously complex and time-consuming. But with a structured content platform, translation times can be reduced as much as 60%⁶, by empowering teams with:



A single platform for managing all language versions

Structured content enables all language versions of components to be stored in the same CCMS which makes it easy to manage and update them. When a component needs to be updated, it's easy to send it for translation and then integrate it back, creating the new localized documentation version.



Precise component-based translation

Instead of localizing entire technical files, translators can manage granular pieces of content, substantially reducing translation costs. This approach also reduces delivery time for the translation teams, as it helps them pinpoint exactly what needs to be translated instantly.



Easy integration with machine learning translation tools

Working with structured content makes it easy for an organization to start working with translation memories (TM). This means that once a content component has been translated, the translated version is saved in the TM, reducing time needed for future translations.

⁶ Tridion data

From documents to data

Only the remaining parts, those that haven't been translated before, need to then be translated and incorporated into the TM tool. Modern digital tools allow the integration of machine translation capabilities in the translation process. This accelerates the process even further by using AI to translate the required passages before being passed to humans for validation.

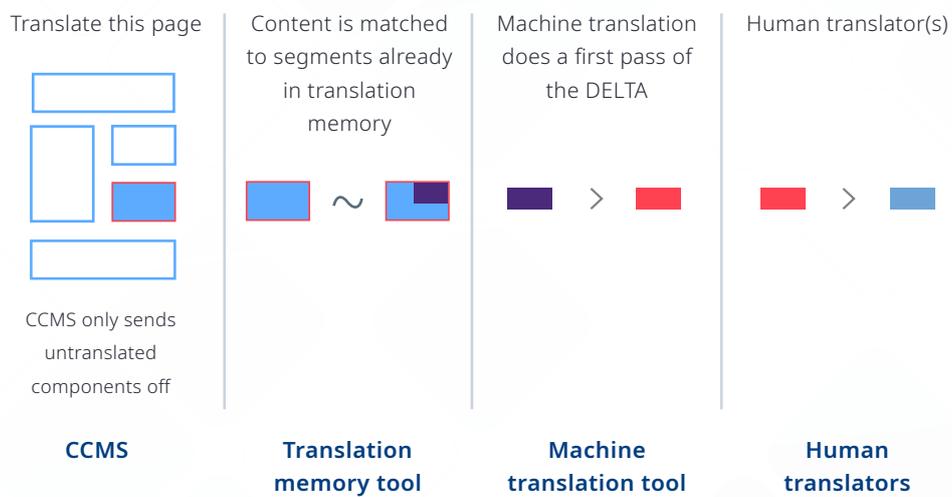


Figure 7: End-to-end translation optimization with human-centric AI tools





Compliant documentation

In a survey conducted by the European Medical Writer’s Association⁷, incomplete content, data errors, nonadherence to guidance and poorly designed tables and graphs are all among factors that negatively affect regulatory application approval.



Figure 8: Document quality issues with the greatest negative impact on application approval

Templating capabilities within a CCMS help ensure that technical medical device documentation is always complete. Templates can be built around prescriptive regulatory requirements, so that every piece of content your team creates is complete and compliant by default. And because those templates are populated with pre-built and approved content components, all stakeholders can be confident that the content they’re publishing and viewing is accurate and up to date.

As regulations change, content components can quickly be updated and propagated to all relevant content automatically. That enables teams to rapidly roll out necessary updates across all their content – cutting the time needed to keep documentation compliant from days to just minutes.

⁷ Source: European Medical Writers Association - Volume 31 Number 2 | June 2022 - Medical Writing



Faster document generation and maintenance

Structured content significantly accelerates document creation by using components to build and manage content. Once document owners define what they want to cover within their documentation, they can quickly and easily pull in pre-approved content modules to bring their new documents to life, and publish them at speed.

With a CCMS, the same content components can be integrated into technical files, and more consumer-facing assets, like medical device screens, product websites or press releases. Teams can create and manage multiple document versions at the same time, ensuring documents in all languages are up to date and complete – while maintaining a clear version log and audit trail for traceability.

Now, generative AI is starting to take that efficiency and acceleration even further. While we're still quite a long way from generative AI tools being able to handle complex and critical medical device documentation tasks on their own, capabilities have emerged that can give writers a lot of support.





Value-based content management with Tridion Docs

Tridion Docs from RWS is a Component Content Management System as described in this whitepaper. It gives you complete control over content at every stage of the medical device lifecycle. You can update content across documents and other output channels through content reuse, and easily adapt to any regulatory changes.

Modular content conforms to predefined rules, which improves productivity, promotes reuse, reduces translation costs and ensures compliance. Content is stored and managed centrally and can be accessed by multiple internal and external departments and contributors – and translated, formatted and delivered to the right output.

Tridion's semantic AI capabilities make it easier to identify the right content in large-volume documents with the help of built-in search, so you can update and create new documentation versions much faster than in a traditional word-processing tool. While creating content, editors can apply smart tags which, together with flexible metadata and taxonomy management, help all documentation stakeholders find the correct information faster.

Our solution is designed to complement your existing eQMS, by offering a single tool for creating, reviewing, approving, updating, managing and publishing content ready to be integrated into your quality management system.

With Tridion Docs, you can drive a value-based approach to medical device documentation. We know that your priority is to deliver ever better medical products while driving down costs. We think content creation and management is the first place you should look to make sure you drive efficiencies throughout your medical device lifecycle, from design to final value for patients.

Those benefits come together to help MedTech companies overcome their biggest content creation and management challenges, accelerate regulatory compliance and, ultimately, bring new devices to market faster.





By adopting Tridion Docs, we have seen customers achieve:

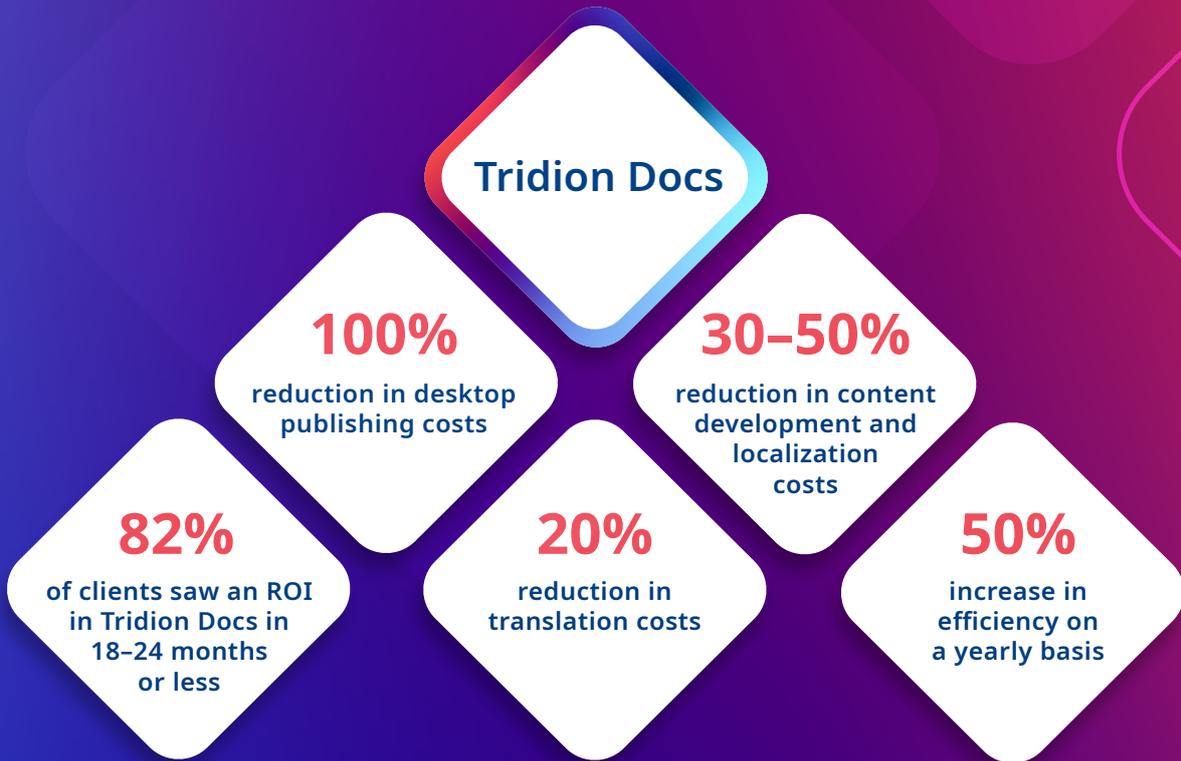


Figure 9: Benefits seen when using Tridion Docs

To learn more about Tridion Docs and discover how it could help you create compliant regulatory submissions for medical devices and IVDs, visit **Tridion Docs for Medical Devices**

About RWS

RWS Holdings plc is a unique, world-leading provider of technology-enabled language, content and intellectual property services. Through content transformation and multilingual data analysis, our combination of AI-enabled technology and human expertise helps our clients to grow by ensuring they are understood anywhere, in any language.

Our purpose is unlocking global understanding. By combining cultural understanding, client understanding and technical understanding, our services and technology assist our clients to acquire and retain customers, deliver engaging user experiences, maintain compliance and gain actionable insights into their data and content.

Over the past 20 years we've been evolving our own AI solutions as well as helping clients to explore, build and use multilingual AI applications. With 45+ AI-related patents and more than 100 peer-reviewed papers, we have the experience and expertise to support clients on their AI journey.

We work with over 80% of the world's top 100 brands, more than three-quarters of Fortune's 20 'Most Admired Companies' and almost all of the top pharmaceutical companies, investment banks, law firms and patent filers. Our client base spans Europe, Asia Pacific, Africa and North and South America. Our 65+ global locations across five continents service clients in the automotive, chemical, financial, legal, medical, pharmaceutical, technology and telecommunications sectors.

Founded in 1958, RWS is headquartered in the UK and publicly listed on AIM, the London Stock Exchange regulated market (RWS.L).

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