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rws

EBOOK

Speed, Compliance, and Cost Control:

The Triple Advantage of Structured Content for Medical Devices

www.contentrules.com | info@contentrules.com

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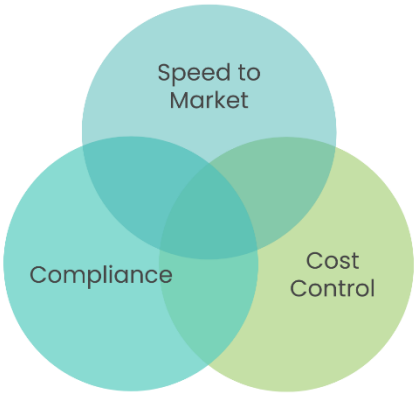
Medical device companies share three nonnegotiable business objectives:

- **Speed.** Increase speed to market, to meet launch dates before the competition.
- **Compliance.** Mitigate risk and satisfy regulators from Brussels to Brazil.
- **Cost control.** Contain costs of delivering multilingual, regionally appropriate device documentation to a wide range of users.



Achieving any one of these goals provides some competitive advantage. But companies that achieve all three objectives – reducing time, risk, and cost -- have a significant lead over their competition.

The good news is, there is one proven solution that empowers your organization to achieve all three goals: structured content authoring (SCA). Based on our experience, innovative medical device companies that have already adopted SCA have achieved outstanding results, ranging from:

- Cutting translation time by 50%
- Reducing publishing time by 75%
- Reducing operational costs by 60%

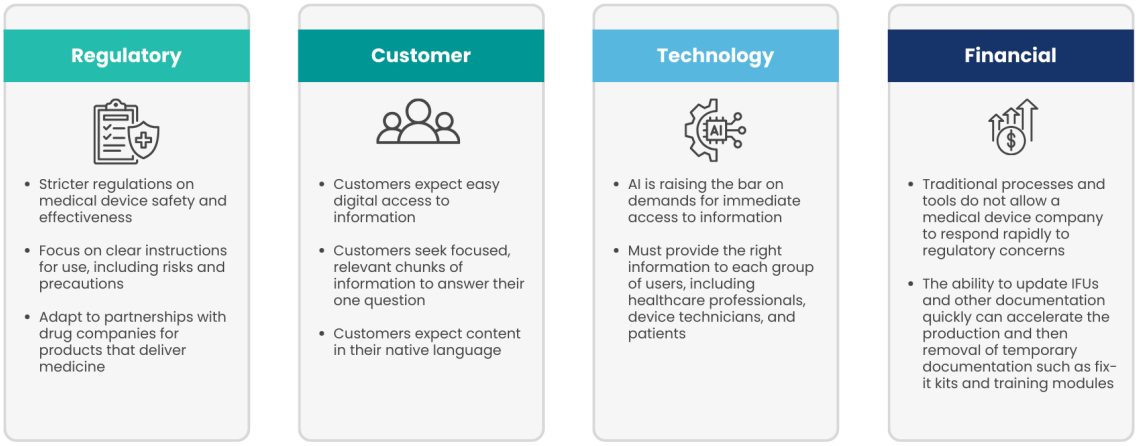
This eBook provides:

- A clear definition of structured content authoring
- Examples of how SCA outperforms traditional processes
- Metrics from medical device organizations that cut time-to-market by up to 50 percent, trimmed translation costs, and tightened audit trails
- A snapshot of a future-ready structured content ecosystem
- Benefits of SCA adoption
- Overview of how SCA helps optimize IFU content for AI

Medical Device Industry Is at a Crossroads

Medical device companies are under increasing pressure to change how they deliver information. This pressure comes from many directions, including:

- Regulatory
- Customer
- Technology
- Financial



Regulatory Pressure

Regulators continue to become more strict about device safety and effectiveness while also requiring unprecedented levels of transparency and traceability to the public. Recent European regulations require medical device companies to provide more clinical evidence to show the safety and performance of their products as part of each application for market authorization. The application must also include more detailed information about the intended use of the device, along with technical information about its design, manufacture, risk assessment results, clinical data, and usability studies.

Products that previously were not highly regulated – such as diagnostic, aesthetic, or monitoring devices – must now undergo regulatory review just like more traditional medical devices. What's more, some devices that were approved under less stringent regulations must undergo a re-assessment and cannot continue to be sold under previous certifications.

Partnerships with drug companies may also be at risk if the medical device company cannot adapt quickly enough to meet global regulatory requirements.

To top it all off, regulators have called upon device companies to provide more accessible Instructions for Use (IFU) for healthcare professionals and for patients. These instructions must include clear descriptions of potential risks and list all necessary precautions.

Region	Regulatory Constraints	Why SCA Helps
EU MDR / IVDR	Clinical evidence ramp-up, eIFU (EU 207/2012), UDI, EUDAMED	• Single-source components feed PDF submissions and digital e-labeling portals.
USA (FDA)	21 CFR 820 (QSR), Part 11 (electronic records), SBOM for cybersecurity, forthcoming AI/ML guidance	• Single-source components feed PDF submissions and digital e-labeling portals.
MDSAP (global)	One audit for five agencies (FDA, Health Canada, ANVISA, TGA, PMDA)	• Metadata-rich topics auto-assemble regional variants.

Customer Pressure

> *Digital-native surgeons and patients want bite-sized answers, not 300-page PDFs. Short how-to videos, searchable portals, and AI chat are essentials.*

At least two generations of healthcare professionals and consumers have grown up with digital access to information. These customers expect to access device information at the touch of a button. They expect to be able to search a digital library, find an answer, and get on with their task as seamlessly as possible. For

complex hardware, they expect short videos demonstrating the correct, safe way to perform procedures.

These consumers are not satisfied by a monolithic PDF that they cannot easily view on a mobile device. Rather, they seek focused, relevant chunks of information that answer their question or can walk them through a task – in their own language, with visuals of their exact device model.

In fact, today, they expect to be able to ask a question of an AI chatbot and receive an answer tailored specifically to their need.

The traditional IFU is too focused on submissions and not optimized for device operators, maintenance technicians, or end users.

Technology Pressure

> *Accessible GenAI means an operator can ask, "How do I recalibrate Model X?" Structured content can return the accurate and on-brand response. Remember the liability is yours.*

The emergence of accessible artificial intelligence (AI) has impacted every aspect of device research, development, manufacturing, documentation, and delivery.

Medical device companies are exploring ways to leverage AI to gain insights into potential new products, recommend new uses for existing product lines, and to accelerate device development and manufacturing. Customers are relying on AI to provide faster, more personalized access to information about selecting, purchasing, implementing, and using medical devices.

Medical device companies must be able to respond to this new demand for information accessibility. They must be able to provide the right information to each

group of users, including healthcare professionals, device operators/technicians, and patients.

Medical device companies must ensure this information is accurate. They must guard against the potential for AI to rely on outdated, inaccurate content. This emerging technology increases risk to the company, as the AI solution may provide users with erroneous instructions, particularly for any case where there is risk of physical harm or equipment damage.

"We had to manage hundreds of outputs from shared content, in multiple languages, for different instruments and customer types."
— Jean–Michel Guillot, Documentation Manager, IVD Diagnostics

13,500 documents in 15 languages

Only 7 writers supporting the entire operation

Types of content: *user manuals, daily guides, contextual help, service manuals, reagent leaflets, MSDS*

Challenges: *explosive content growth, new variants per product, and scaling with increasing SKUs*

Outcome*: cut translation spend by* ***50%****, eliminated DTP, supported structured reuse*

Financial Pressure

Nobody wants to add up the exact cost of a medical device issue that stops the company from being able to ship the device. Some estimates put the cost at a million U.S. dollars per day. "Astronomical" is not an exaggeration. The cost can be measured in a number of areas throughout the business, including storage costs, loss/breach of contract, loss of first-to-market, patents, lawsuits, and a myriad of other direct and indirect expenses of mitigation.

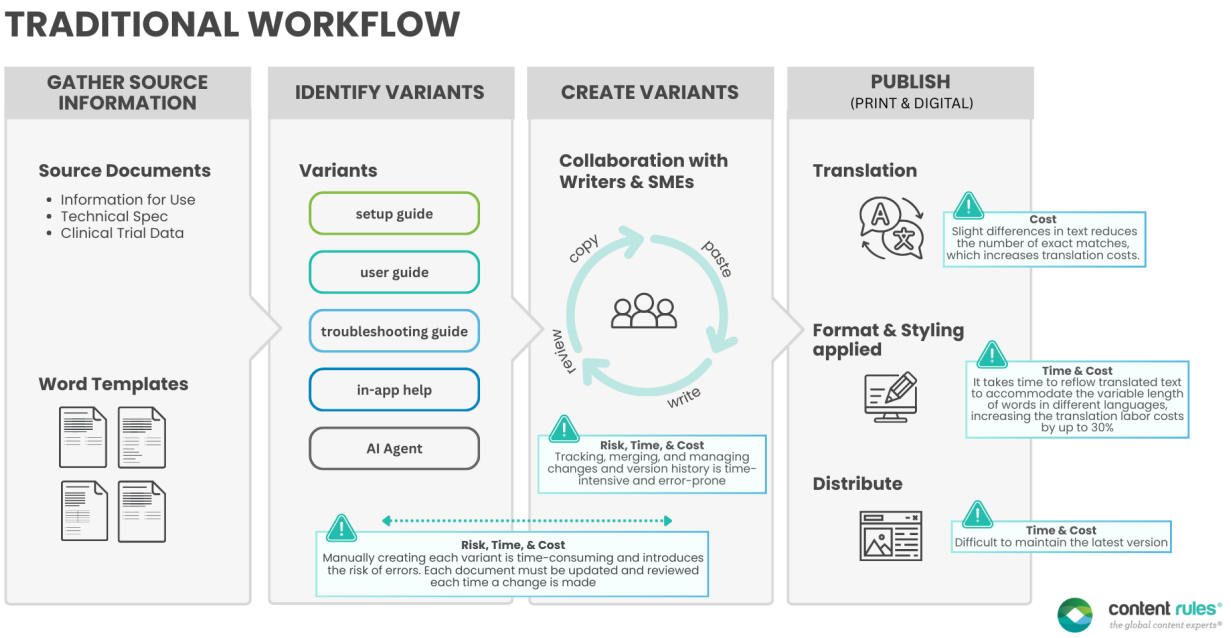
Unfortunately, the traditional way of managing IFUs as a collection of standalone, monolithic documents adds to this extreme expense. Traditional processes and tools do not allow a medical device company to respond rapidly and get the device back into production or on the market.

In contrast, the ability to deliver new documentation quickly provides a huge financial advantage to medical device companies. For any risk that can be addressed by documentation – a new safety warning, a revised set of instructions, a different illustration – every day shaved off the document update and verification cycle means a faster end to the cash hemorrhage and a rapid return to revenue generation.

Likewise, for risk mitigation through product redesign, the ability to update IFUs and other documentation quickly can make a significant contribution to the bottom line. Accelerating the production and then removal of temporary documentation such as fix-it kits, and training modules can also make a noticeable financial impact.

Traditional Documents Are Costly and Slow

The traditional Instructions for Use (IFU) document includes a wide range of information intended for a wide range of users. A typical IFU may combine safety warnings for installers, operators, maintenance technicians, and consumers into a single Safety section. It provides chapters for setup, operation, maintenance, and troubleshooting tasks, even though operators are often not the same people performing maintenance or troubleshooting.
Delivering an IFU as a large, all-in-one document is convenient for medical device



companies and regulatory reviewers who want to see all information in the same place.

However, a monolithic PDF is not the ideal way to support the people who use the information. With one big PDF, each user role must access the document, search or browse to find the section relevant to the task at hand, and then drill down further to find the exact instructions they need.

Compare that experience to a quick search of a web portal and you begin to understand how the traditional IFU fails to serve modern users.
More than 75 percent of healthcare professionals in the United States are under the age of 60. According to the U.S. Bureau of Labor Statistics[1], over two-thirds of healthcare professionals were between the ages of 25 and 54 in 2022. Another 12 percent of healthcare professionals were aged 16 to 24. These workers represent three generations – Gen X, Millennials, and Gen Z – that have grown up with a high level of expectation that information is available, accessible, and searchable.

To serve customers better, many companies produce additional documentation. Consumer devices often come with a quick start guide to help an end user set up and start using their device. For professional equipment, a separate maintenance manual may be provided for technicians. This documentation places additional burdens on content teams who create, update, and release the documents.

Today's practice of authoring the IFU and every related output as separate, complete documents does not scale. The process is based on print publishing traditions where each document is created, reviewed, approved, formatted, and published as a unit. It involves lots of manual steps that can be done today much more effectively and efficiently through automation.

Traditional IFU Pain Points

- Monolithic PDFs are difficult to search and hard to view on mobile devices
- Every language version re-translated, even when 90 percent identical
- Desktop publishing bottlenecks add multiple days or weeks per revision
- Entire documents must be verified and validated for a single line change

Result: slow updates, high cost, unhappy users

[1] Spotlight on Statistics, U.S. Bureau of Labor Statistics, published June 2023. Accessed 1 April 2025. https://www.bls.gov/spotlight/2023/healthcare-occupations-in-2022/

The astronomical costs of a stop shipment and recovery can include:

- Initiation of stop-ship and field repair procedures
- Idle factories
- No new sales
- Contract penalties
- Lost market share: incalculable morale damage
- Cost of research and development for the fix and/or a redesign
- Production of a temporary "fix kit," which includes documentation and training
- Update and republish IFU, packaging, training, parts catalog, app, device software UI and help, SOPs
- Translate and republish all new and updated content
- Resubmission to health authorities

When you add up these costs of responding and recovering, you see the clear value of adopting structured content. A structured content ecosystem enables east and frequent updates to IFUs and other device documentation, in every language, in every output format and platform.

Unlocking the Value of IFU with Structured Content

Many RWS customers in the medical device sector produce **hundreds to thousands of content variants.** They deliver content in 15 to 40 languages. They deliver multiple output types, providing documentation for consumers, healthcare professionals, technicians, regulators, and so on. By adopting structured content authoring and the RWS Tridion Docs solution, these organizations reduced translation and publishing time **by weeks**, while enabling reuse and scale without increasing team size.

But don't take our word for it. RWS customers' results speak for themselves:

Content reuse ↑ (60%): Waters achieved up to *60% reuse* of existing source content (Case study: Waters saves time and cost with ±60% content reuse | RWS), dramatically reducing new writing. Meyn targeted 25% reuse (Meyn case study). (With modular topics, once-written content can populate

Validating 800+ Variants		
	Scenarios	Translation Challenges
HORIBA Medical LIFE SCIENCES/ IVD DIAGNOSTICS	• 13,500 docs, 15 languages • 7 writers • User, service, and MSDS docs • Explosive content growth	• Variants per product type • Scaling IFUs/doc count with SKUs • On-brand PDF output • Faster change management
PHILIPS Image-guided therapy MEDICAL DEVICES	• IFUs in 35 languages • Clinical + educational reuse • On-brand PDF output • Faster change management	• Multi-output publishing • Rapid rollouts without extra staff
HACH LIFE SCIENCES-ADJACENT	• IFUs in 27 languages • Dual-branding requirements • 20 books x 23 EU languages • 460+ versions	• Dual branding localized docs • Large-scale push-button publishing

multiple manuals, as one customer says: *"With Tridion Docs in place, we can look to the future, to re-using content…"* (Philips case study).

Translation cost ↓ (30–50%+): Horiba cut its translation spend in half (Tridion Docs Horiba Medical case study), while Meyn anticipates a 30–50% reduction (Meyn case study). Integrated workflows and reduced redundancy (no more re-translating identical content) drive these savings.

Publishing time ↓ (~99%): Automated publishing compresses schedules from days to hours. One example cut a 12.2-day process to roughly 5 hours total (Tridion Docs Horiba Medical case study). (Even without precise numbers cited, multiple case studies highlight "automated publishing" and "push-button" outputs as game-changers.)

Editing speed: Tridion Docs' XML authoring and direct tools access let tech writers make global changes in minutes. Philips notes the *"ability to quickly make changes via direct access to tools"* (Philips case study), keeping documents up to date without new headcount.

Operational costs ↓ (e.g. 60% hosting): CommScope consolidated dozens of legacy systems into one CMS, cutting hosting costs by 60% (CommScope Case Study - RWS). (While the exact figure is from an RWS case study search, it aligns with multiple customers reporting major IT savings through consolidation.)

The Future of Structured Content Authoring

The good news is, medical device companies can meet the needs of regulators, healthcare professionals, investors, and consumers by changing their approach to IFUs and related documentation.

There is a tried-and-true way for enterprises to meet increasing demands for content, tailor content to each audience, and ensure data traceability and a

complete audit trail throughout the end-to-end content lifecycle: **structured content authoring**.

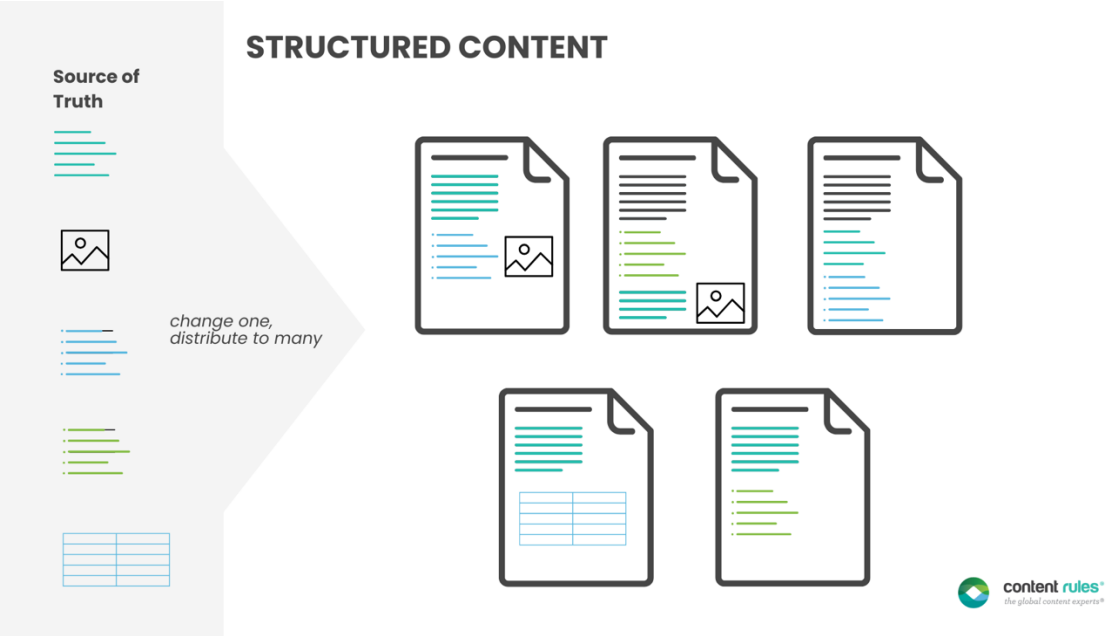
For example, Image Guided Therapy (IGT): "Ability to translate into 35 languages with the same headcount… eliminated desktop publishing costs."— *IGT case study*

- IFUs delivered in **35 languages**
- Two major use cases: clinical and educational reuse
- Required “on-brand” PDFs, multi-output publishing, and fast change management
- Maintained output scale with the same number of tech writers and translation managers
- Outcome: faster updates, zero DTP, reuse across business units

What is structured content authoring?

Structured content authoring (SCA) is the practice of capturing knowledge in a set of individual knowledge assets, typically called “components” or “chunks.” These components of information can be assembled automatically in many different ways and published to many different outputs.

With structured content authoring, each component of information is created only once. It is reviewed, approved, and released for use. It can then be included everywhere that information is required.



For example, a component that provides a series of steps for how to reset a device may be included in a traditional IFU, a maintenance manual, an in-app Help system, a support portal, and via an AI agent or chatbot. The instructions are written, reviewed, approved, translated, and released once. If they must be updated, that

single component gets updated. The updates are automatically made available everywhere that component is used.

Why adopt structured content authoring?

The reason we structure content is to make the content ready for machine processing. Well-structured content is consistent and standardized so that computers can perform tasks with little or no human intervention.

Structured content is typically implemented by applying some form of *markup* to the content. In this context, markup simply means a set of labels or tags that identify content by its characteristics rather than by how it looks or which document it was created in. Content characteristics typically include criteria such as content type and intended audience.

For example, IFUs typically include at least three content types: conceptual content, procedural content, and reference content. Different chunks of content within an IFU typically have one or more of the following intended audiences: regulators, healthcare professionals, device technicians, device operators, or consumers.

What does “machine processing” mean for IFU content?

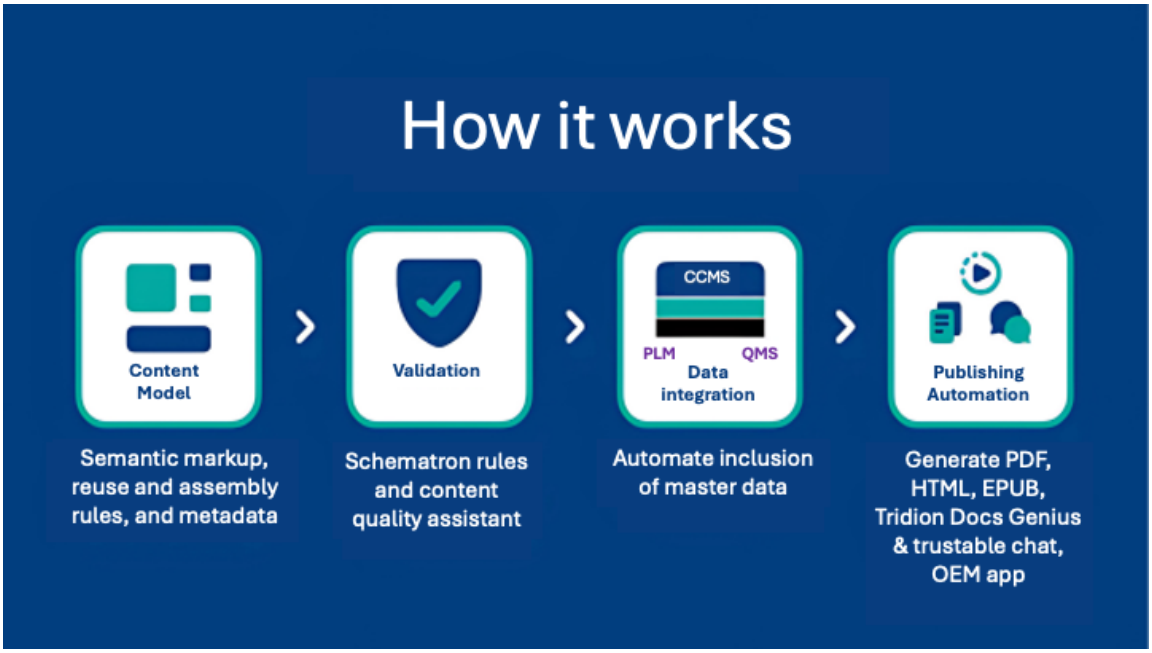
Machine processing is a catch-all term for content reuse and automation. Here are a few examples of how innovative medical device companies automate content production with structured content authoring:

- Create device IFU and related documents from standardized templates
- Reuse content within and across device documentation and training
- Apply formatting, layout, and pagination
- Retrieve regulatory and device data stored in RIM, QMS, or other systems
- Track every change throughout the content lifecycle
- Review content collaboratively in a single source
- Manage translated text in the same system as source language text
- Publish documents, web pages, and app content in multiple languages from a single source
- Harmonize branding and terminology across various product lines, especially after mergers and acquisitions

Structured content authoring unlocks the value of your IFU by making each component of information reusable. You quickly can publish the components to the traditional IFU document format as well as to digital channels of content delivery.

How It Works

1. **Content model** – Semantic markup, reuse and assembly rules, and metadata identify content for machine processing
2. **Validation** – Schematron rules and content quality assistant ensure compliance at authoring time
3. **Data integration**– Tridion Docs integrates with PLM, QMS, RIM to automate inclusion of master data and reduce need for re-verification
4. **Publishing automation** – Generate PDF, HTML5, EPUB, JSON, and push content to OEM apps.



The Benefits of Structured Content Authoring

Structured content authoring (SCA) provides many opportunities to reduce content development time, reduce translation costs, and reduce risk. The result? Faster time-to-market and rapid response should issues occur that stop shipment temporarily.

Reduce Time

- Reuse content.
- Automate publishing (formatting, design, layout, navigation).
- Streamline MLR review.
- Generate new templated documentation from content repositories using AI.
- Efficient verification and validation processes.

Reduce Cost

- Contain translation costs
- Eliminate desktop publishing (source + local languages)
- Respond rapidly to issues
- Reduce call center costs

Enter New Markets

- Assemble new outputs quickly
- Deliver personalized content
- Leverage emerging consumer med-tech market
- Add new languages faster

Reduce Risk

- Respond rapidly to market events
- Track data flow with full traceability
- Manage risk mitigation
- Improve CAPA processes

Serve Customers Better

- Provide consistent messaging across documentation and training
- Improve findability and access to information in all languages
- Improve AI accuracy

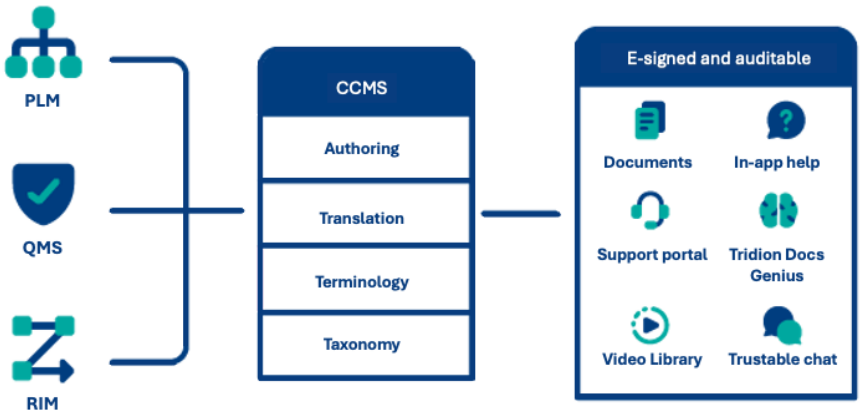
Streamline Regulatory Audits

- Provide detailed version history.
- Respond to audit questions with AI.
- Automate audit reports.
- Leverage AI to search data sources and structured content repository.
- Granular tracking of reasons for change.

What About AI?

Medical device companies that adopted structured content authoring (SCA) early have a head start in optimizing their content for use with AI. Why? Because these companies already create, store, and manage their content as a collection of knowledge assets, typically called "chunks" or "components." These knowledge assets are the foundation for training AI solutions and optimizing content for retrieval-augmented generation (RAG).

With the advent of AI, structured content authoring has become a business imperative.



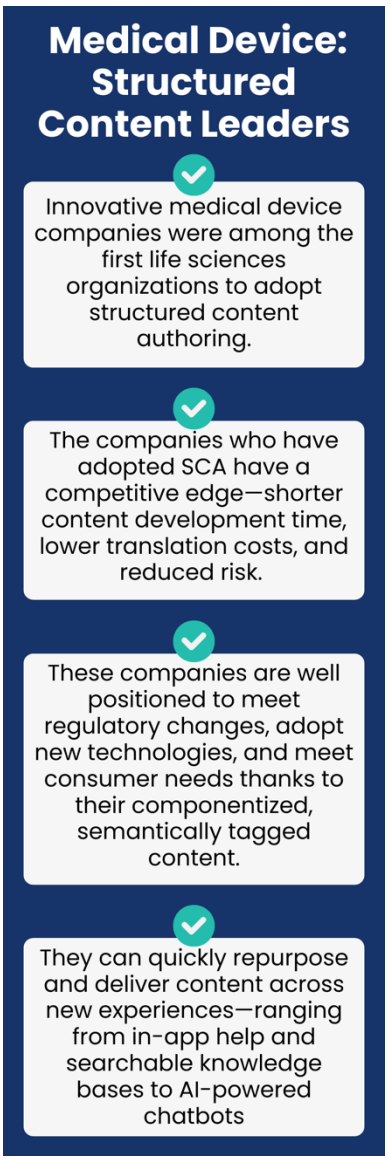
We Can Help

There are many reasons to adopt structured content authoring as soon as possible. Perhaps the most important is the ability to pivot quickly to meet evolving regulations. A close second? The competitive advantage of reducing time to market by automating as much of the content lifecycle as feasible. Thirdly, the cost savings in content development, translation, and desktop publishing cannot be achieved in any other way.

And without structured content, the use of AI will likely exacerbate problems rather than accelerate process.

The good news is, Content Rules and RWS bring decades of experience guiding companies through this digital transformation.

Content Rules can lead the project, develop your content architecture and reuse strategy, and train your team so that they can get to work in the new content ecosystem right away. Content Rules will guide you through the transformation and into operations as efficiently as possible. We have proven methodologies to help your organization overcome common barriers to adoption, such as resistance to change or lack of experience developing a new way of working enabled by technology. Contact us today to begin your transformation journey.



RWS provides best-in-class technology and services to enable automation at every stage of the end-to-end content lifecycle for medical devices. RWS Professional Services and Customer Success teams offer follow-up, continued help, and resources after the content transformation. RWS offers teams of trained professionals who will always be by your side to continue optimizing your system, content, and usage so you are not left on your own.

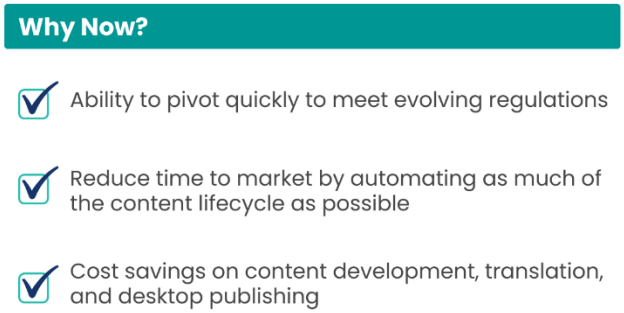
Adopting structured content authoring does require an initial investment. Creating a scalable, optimized content process takes expertise and time. However, with today's

proven methodologies and toolsets, the adopting structured content is not nearly the heavy lift it used to be. Content Rules and RWS are poised to help you get there as quickly as possible, with the least amount of disruption. Learn more.

Conclusion

To remain competitive and better serve the patient population, the medical device industry needs to:

- Reduce product development cycle time.
- Contain operating costs.
- Enter new markets.
- Reduce risk.
- Serve customers better



Structured content authoring enables medical device companies to automate creation and production of medical device content. By adopting structure now, you prepare your content to meet changing regulations, serve different audiences, and optimize for AI.

Get In Touch

Adopting structured content authoring is an investment in digital transformation that can pay for itself in as little as a year after getting into production. Content Rules and RWS bring mature methodologies and best-in-class technology to help our customers implement SCA as efficiently as possible, with minimal disruption and at reasonable cost. Contact us today to begin your transformation journey.

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the global content experts®

About Content Rules

We're content experts who have held the leading edge in our field since we opened for business in 1994.

The world's largest and most innovative companies trust us to develop their enterprise content strategies, transform their content ecosystems, optimize content for a worldwide audience, and develop effective content that gets results.

Content Rules has the knowledge and experience to deliver the highest quality content services every single time.

Our services include proprietary methodologies owned by Content Rules, Inc. Please do not share or distribute information pertaining to these services without express written permission from an authorized representative of Content Rules, Inc. These proprietary methodologies include: (1) Five Dimensions of Content Standardization™ Framework, (2) The Rockley Method™ of Unified Content Strategy, (3) Content Rules Content Transformation and Migration™, (4) Content Rules Anatomy of Change Model™, (5) Content Rules Structured Content Authoring for Pharma™ Methodology.

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About RWS

RWS is a content solutions company, powered by technology and human expertise. We grow the value of ideas, data and content by making sure organizations are understood. Everywhere.

Our proprietary technology, 45+ AI patents and human experts help organizations bring ideas to market faster, build deeper relationships across borders and cultures, and enter new markets with confidence – growing their business and connecting them to a world of opportunities.

It's why over 80 of the world's top 100 brands trust RWS to drive innovation, inform decisions and shape brand experiences.

With 60+ global locations, across five continents, our teams work with businesses across almost all industries. Innovating since 1958, RWS is headquartered in the UK and publicly listed on AIM, the London Stock Exchange regulated market (RWS.L).

More information: rws.com