Tridion Docs for Medical Devices

Structured content for medical device manufacturers to ensure productivity, compliance and shorter time to market

RWS Tridion Docs

Your medical device documentation: accurate, consistent and compliant

Creating and distributing technical medical documentation at scale can quickly become an unmanageable task. The information you provide for your medical products – whether it's via marketing materials, labels, instructions, clinical evaluations or regulatory reports – needs to be highly detailed, accurate and easy to access. And what's more, this documentation must be consistent across all languages, channels and devices.

The challenge: A document-centric approach

Authoring a document like a regulatory submission or IFU, circulating a draft for review and manually consolidating all the stakeholder comments before sending it for translation is no longer the most efficient approach.

Medical professionals, patients and researchers must have quick and easy access to the most up-to-date information about how to use the device. And auditors and regulators need a full view of your documentation to ensure compliance and process regulatory submissions efficiently.

For medical device documentation to be truly useful and accessible, the production process must be faster, more flexible and have the ability to scale in a cost- and time-effective way.

The solution: A structured content approach

To offer your employees a more agile, iterative way of creating documentation and ensure users can access the information they're looking for, you need to start by redefining your content supply chain.

With Tridion Docs, you can centralize the creation, translation and delivery of all your content types. It helps you organize all your information in a structured way, using predefined modules and relationships to build your content from a single source of truth.

Tridion Docs allows you to easily reuse, share, filter and deliver any piece of multilingual content – from a single paragraph to a 1,000-page document – to any channel.

A single source of truth for your medical device information accelerates your global content supply chain

With Tridion Docs, you can create, manage and deliver in-depth information about your devices at scale using a structured content approach

The content you produce for your devices will likely overlap in multiple channels, which raises a major challenge. The information needs to be consistent and up to date in every touchpoint but, if you don't have the right processes in place, this can lead to extensive reworking – especially if your content is available in multiple languages.

Structured authoring allows you to build content with reusable modules – or components – which can be repurposed in multiple publications. And enabling reuse early in the process maximizes the benefits.

For example, a description for a component in a CT scanner written during the development process could be reused later in a service manual. Or, input from a clinical evaluation report could feed into a regulatory submission to provide further detail about a continuous glucose monitor. In both cases, reuse would help ensure consistency and save time and effort ahead of the device's launch.

Tridion Docs is a DITA-based component content management system, which stores and organizes information about your devices as topics. This approach allows you to reduce the volume of source content while ensuring each of your channels are served with highly detailed documentation.

With its scalability, simplicity and automation capabilities, Tridion Docs helps you manage your content library with accuracy, efficiency and governance at the forefront. It's a collaborative system, which means multiple teams can work side-by-side to plan, create and review documentation in a highly agile way.

Structured content leads to shorter development timelines and can reduce translation and publishing costs by as much as 50%

How Tridion Docs transforms your content processes

Streamline your content operating model and remove the bottlenecks with Tridion Docs's market-leading capabilities in every phase of the production process.

Create and manage

- Centralized structured content authoring
- Content reuse
- Publication and baseline management
- Conditional text

Your authors can use their preferred tools, from complex XML editors to simple browser-based word processors. They don't need to be XML experts, as Tridion Docs manages the underlying structure in the background while they author and review documents.

- **Dynamically assemble deliverables** in any output format from a single source, whether it's a PDF user manual or a regulatory submission
- **Baseline Manager** grants you rigorous control over every version of a document, helping you map dependencies between your content and ensure accuracy
- **Condition Manager** offers further precise control over conditional text within the document variants you produce for different device models, markets or applications

Collaborate and review

- Easy authoring for SMEs
- Streamlined workflows
- Cross-team collaboration
- Compliance and auditability

Subject matter experts are a critical part of the content creation process, applying their knowledge to ensure each device is accompanied by the relevant medical information, technical input and regulatory requirements.

To empower this collaboration, Tridion Docs offers:

- **Collective Spaces,** an online environment that allows authors to collaborate in real time, with no need for cumbersome PDF markup
- **Review overlays** that allow multiple stakeholders to provide feedback on the same document simultaneously, consolidating their input from the first instance
- **Threaded conversations** to keep feedback discussions focused and in a single channel

Comply and report

- Simple, componentized regulatory submissions
- Full traceability
- Secure access for auditors
- Data integration for reporting

Regulatory submissions are a consistent bottleneck for medical device manufacturers, as even the smallest inconsistency can lead to a rejection. Tridion Docs creates an environment where compliance is built into the content authoring process, with:

- **Submission templates** which flow in content automatically, ensuring consistency and correct formatting
- **Change logs** that record all changes to a document for full traceability and auditability
- **Secure access** which allows regulators to provide feedback as easily as internal teams to accelerate compliance

Translate and localize

- Integrated translation management
- Translation reuse
- Translation reporting
- Multilingual publication management

Translations are a critical, but often costly, part of the content delivery process. And when you're supplying medical equipment to multiple markets, there's no room for mistranslation.

With Tridion Docs, you can manage translations directly from the platform with:

- **Multilingual controls** to manage publications with more than one language and reuse existing translations
- **Translation management system integration** that allows content to be submitted directly from Tridion Docs
- **Templated output** for multilingual content to eliminate expensive desktop publishing

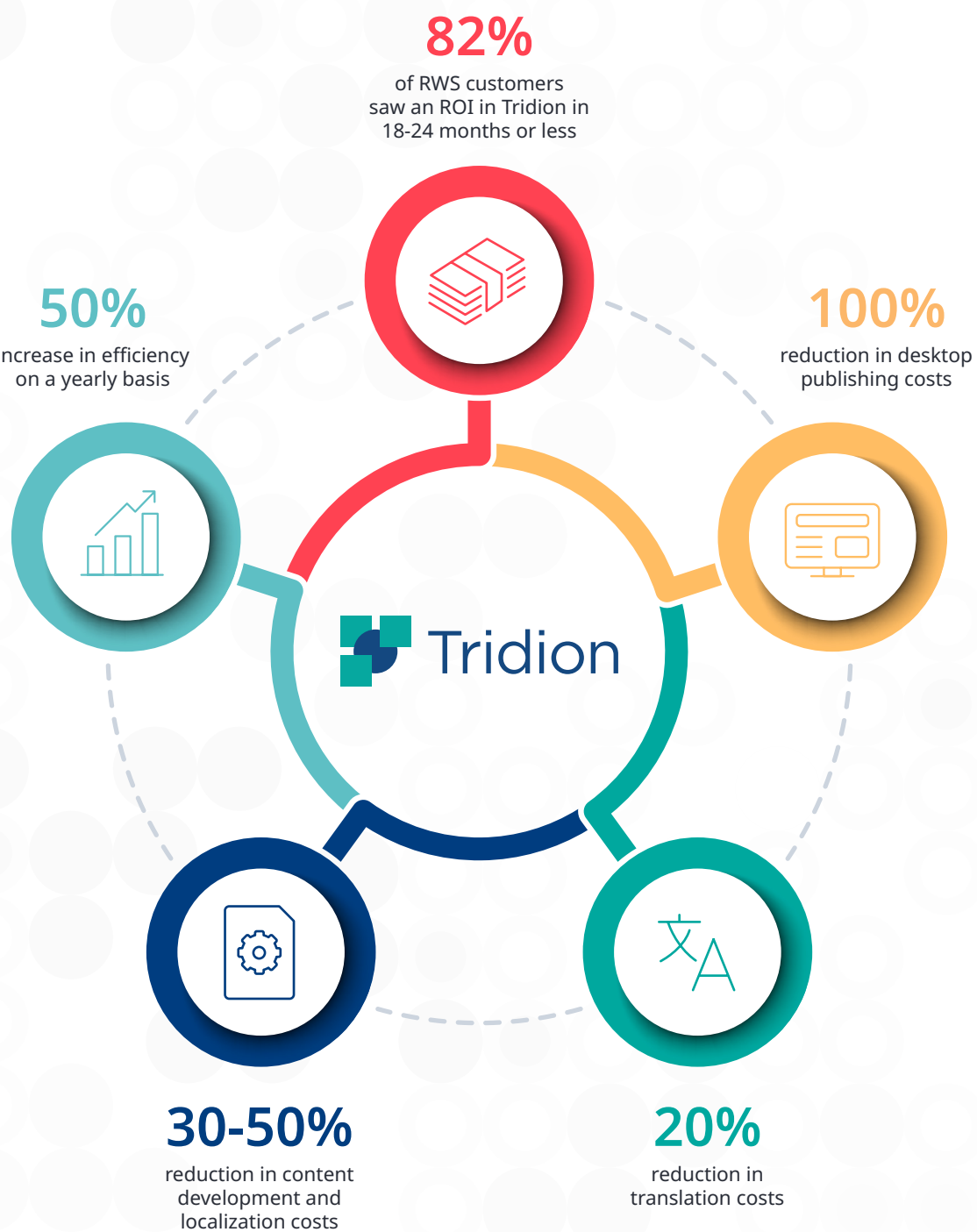
Deliver and distribute

- Single-source content delivery
- Omnichannel publishing
- Content variations
- Contextual delivery

As well as traditional content formats such as PDF, Tridion Docs can support content on any channel and device, with:

- **Dynamic Documentation**, a fully responsive, out-of-the-box digital documentation portal
- **Headless content APIs** that can deliver personalized content to any digital touchpoint
- **Simple scalability** to support digital content distribution on a global scale

Discover the quantitative benefits of Tridion



Discover how you can streamline your global medical writing processes with Tridion Docs

Learn more at rws.com/tridion/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 40+ 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 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).

For further information, please visit: **www.rws.com**

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