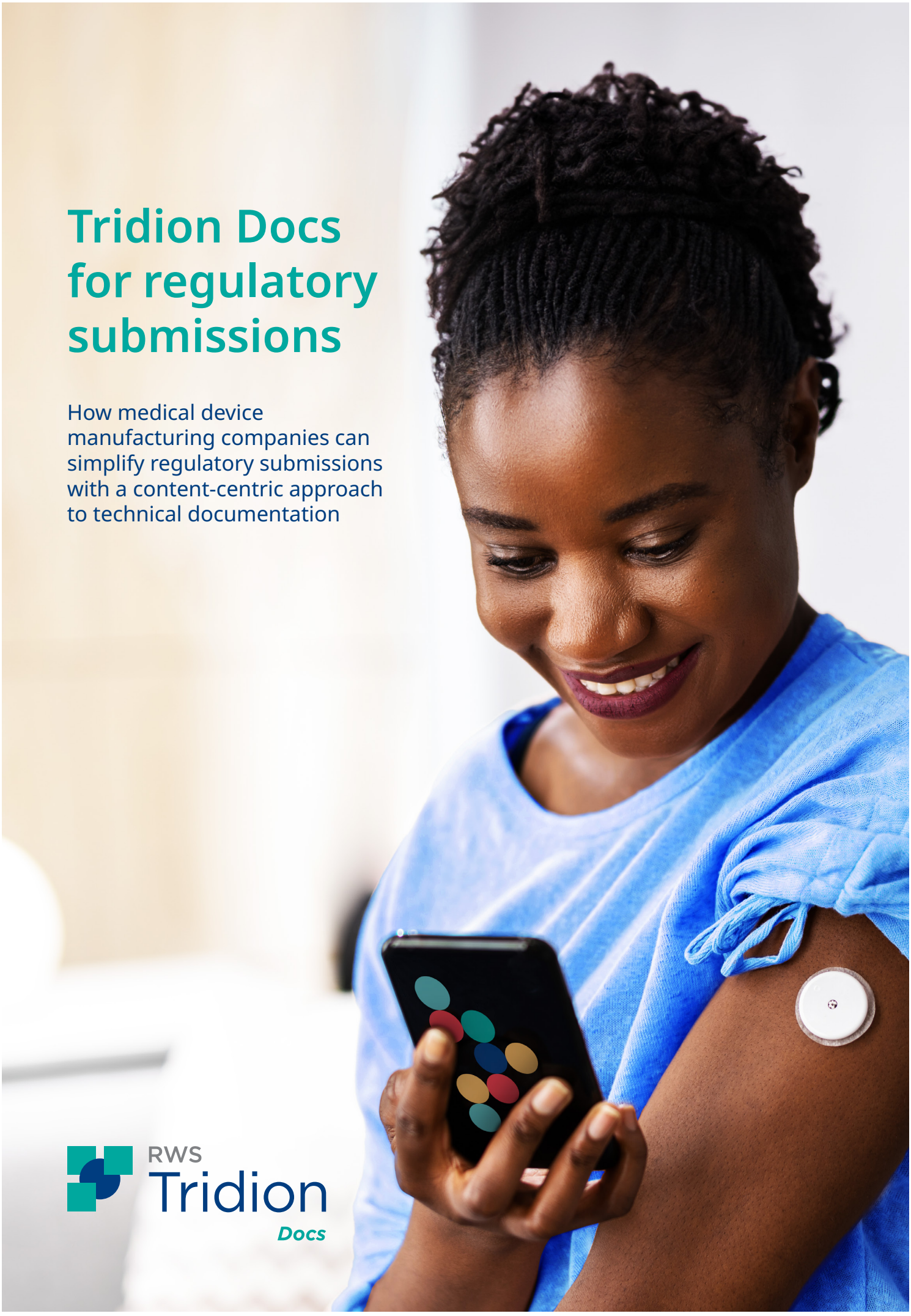
Tridion Docs for regulatory submissions

How medical device manufacturing companies can simplify regulatory submissions with a content-centric approach to technical documentation



RWS Tridion Docs

Creating technical documentation that's fit for regulatory submissions can be challenging. It needs to be organized, clear, unambiguous and readily searchable.

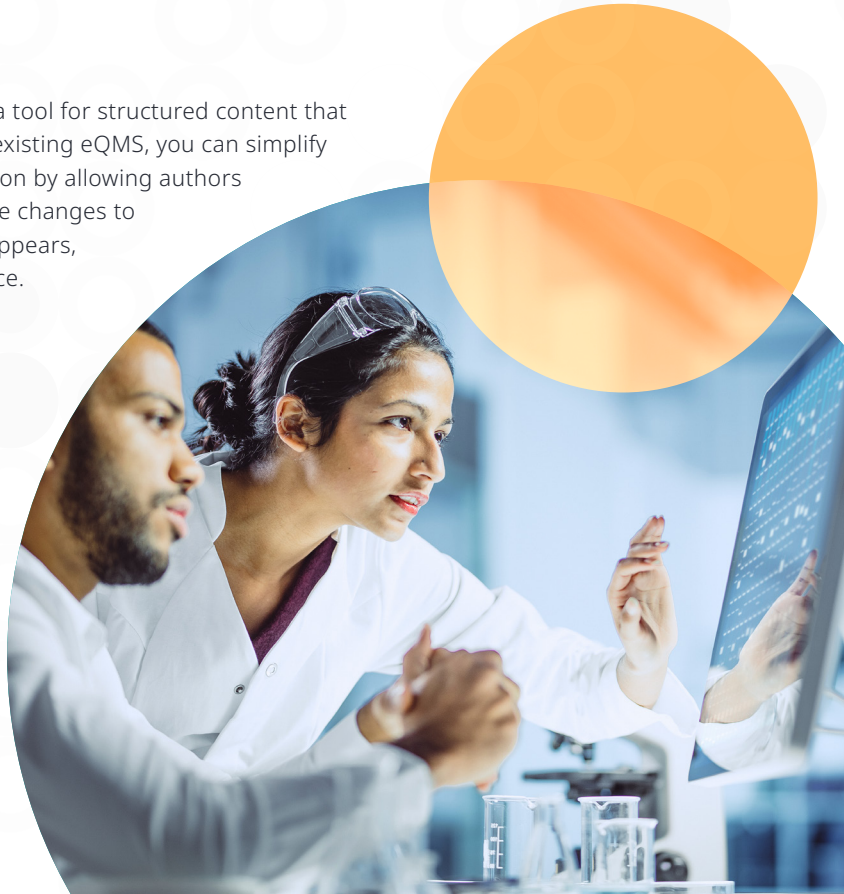
To meet these criteria, your teams must collaborate efficiently with regulatory bodies to ensure you're providing evidence of conformity to strict legal requirements. But too often, this collaboration is held back by outdated content creation workflows and paper-based document control processes.

However, with a content-centric approach to technical documentation that relies on structured content and operates within your existing eQMS, you can enable faster time to market, more successful approvals and greater traceability.

What matters: Internal teams and regulatory bodies need to collaborate as efficiently as possible to create technical documentation that's organized, clear and compliant with ever changing regulations such as EU MDR and IVDR.

The issue: Too often, authors and reviewers are forced to work using inefficient methods such as copying and pasting information between documents – creating opportunities for inaccuracies, inconsistencies and compliance risks.

The solution: Using a tool for structured content that integrates with your existing eQMS, you can simplify documentation creation by allowing authors and reviewers to make changes to content wherever it appears, all from a single source.



A need for more efficient and accurate regulatory submissions

Creating technical documentation with complete, relevant information is essential for every medical device's lifecycle. The documentation needs to meet strict legal requirements and standards specific to the device's market, but producing its content can be an inefficient process.

It often requires specialists to copy and paste information between documents and work across multiple file versions. For example, if the components used in a glucose monitor change between models, every instance where the components are mentioned in the device's documentation would need to be updated across multiple files.

Greater challenges for content authors

The traditional approach to documentation creation often also forces authors to work on platforms that don't support concurrent authoring and reviewing or are not integrated.

While common workarounds involve authors sharing versions with each other using email and file-sharing tools, it's an approach that can quickly lead to inconsistencies, inaccuracies, poor change tracking and greater compliance risks – and a potential downstream risk to patients if any information is wrong.

For example, the content team might be using electronic data capture (EDC) software that doesn't integrate with a stakeholder's regulatory information management (RIM) tool. This adds extra manual tasks to the workflow and puts the team at risk of errors while they copy and paste data between the systems.

And when authors are forced to work with paper-based documents, the challenges become even greater. It's even more difficult to create transparency over the authoring process and it's hard to assess whether documentation even has the right information.

To meet regulatory requirements and standards confidently – and meet the quick turnaround times expected in the market – medical device manufacturing companies need an alternative approach.

The cumbersome shift toward digital content for regulatory submissions

There's a significant push in the medical devices industry towards electronically submitted market approval applications and other regulatory submission documentation. While this is progress from paper-based documents, it's still a push in the wrong direction.

PDFs are quickly becoming the norm for many companies, but this format only offers a static view. When changes need to be made to a file, authors need to create a new version.

Updating information across individual documents is an inefficient process that's prone to errors. And PDFs only add greater hassle for reviewing bodies, who often struggle to access and extract information for internal review templates.

In an area as crucial as regulatory submissions, there's little room for errors. Regulatory bodies will reject submissions that are incorrect, incomplete, inconsistent or poorly formatted. And failure to comply with their requirements could lead to higher charges and increased market approval costs.

This is where structured content can help.

Key areas for improvement

The top three areas for regulatory modernization in the next two years, according to the medical technology industry, are:

62% single source of truth

57% global content reuse

51% centralized RIM platform

Source: Veeva MedTech, *2022 Year-end Regulatory Benchmark Report*, Feb 2023

These are all clearly closely related. Most medical device manufacturers recognize that they need a single source of truth that lets them avoid content duplication. Otherwise, they simply can't secure their critical information against unintended change or content drift that ultimately leads to inconsistencies or inaccuracies.

Structured content offers a smarter approach

Structured content helps you manage information dynamically and simplifies regulatory submissions.

Using versioned, reusable, modular components, rather than content that's duplicated across individual parts of a device's documentation – such as its instructions for use and a troubleshooting section – it's easier to produce documentation that's accurate, consistent, clear, and easy to search and review. It also ensures document control compliance and provides full process transparency.

Streamline document control and collaboration

Taking a structured content approach gives you an opportunity to streamline the document control process across several key areas:

Reusing content

Any changes you make to the source content can be automatically applied to any other related documentation that contains the same information, such as content describing its components, materials, manufacturing processes and packaging.

Supplying evidence

Using the right structured content platform, you can integrate real-world evidence in your regulatory submissions and technical file documentation – such as 510(k) notifications, De Novo classifications and clinical evaluation reports (CERs) – including audit trails and edits made.

Reviewing content

When one of your specialists or external reviewers needs to assess a certain piece of content, such as details on sterilization for a laparoscope, you can route those specific content chunks to be reviewed and approved to them. This eliminates the traditional approach of sending and marking up entire documents, that – when done by multiple reviewers – need to be consolidated manually by the author.

Automating publishing

And by integrating machine-ready data into AI-enhanced workflows, you can publish and distribute this information in multiple formats. This can include submission and materiovigilance forms such as periodic safety update reports (PSURs), labelling templates, digital devices and patient-facing outputs.

The benefits of using structured content

Using structured content, you can:

Accelerate time-to-market

Achieve content reuse by up to 60%

Improve the quality and consistency of your documentation

Enable efficient collaboration, both internally and with regulatory bodies and consultants

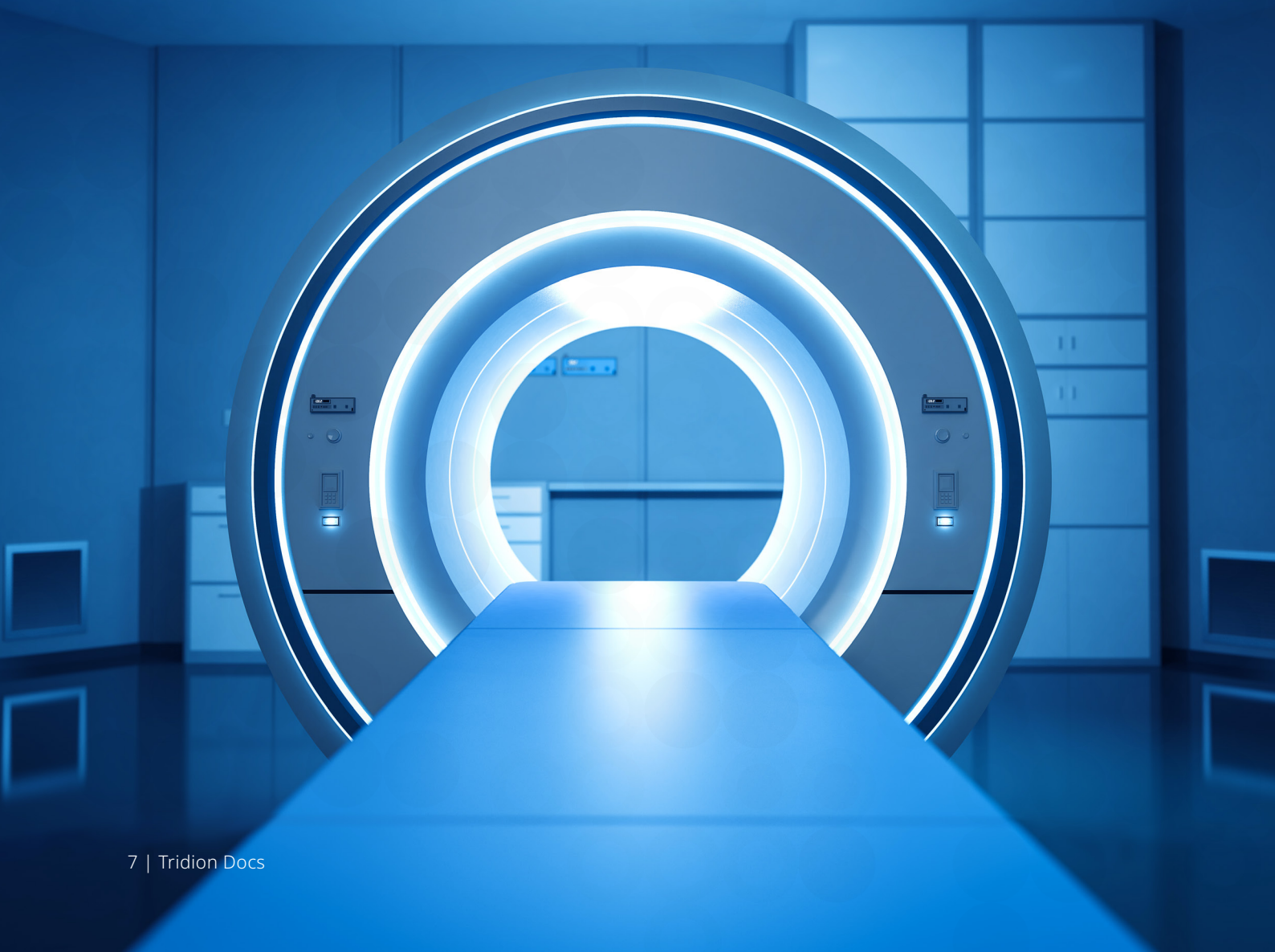
Lower translation costs and speed up the localization process by 60%

Tridion Docs – An end-to-end documentation solution for regulatory submissions

Tridion Docs is a complete documentation solution that makes regulatory submissions faster and reduces the time required to produce technical documentation, taking advantage of a structured content approach.

You can give your authors, subject matter experts and regulatory body reviewers granular control over their technical content. This creates improved productivity thanks to integrated translation management, a baselining feature that offers greater traceability through content versions and variants, and industry-specific taxonomies for more effective governance.

And crucially, it doesn't replace your eQMS. Instead, it offers a more effective alternative to simple word-processing tools and integrates effectively with the document and quality management systems you're already using.



How Tridion Docs transforms your regulatory submissions process

Accelerate time-to-market with compliant documentation – Easily create regulatory submissions that are well structured with the right templates, offer clear identification of documents, contain relevant information, and are complete, so you can gain approval faster.

Streamline collaboration workflows with regulatory bodies – Allow external reviewers to easily access your documentation, identify the sections that need to be revised and leave precise feedback for your authors on their content. Also, using auto-tagging, you can make content much easier to find for everyone involved.

Improve content reusability – Import data from external sources, such as product manufacturing specifications and clinical trials, into specific content components. And with dynamic data integration, you change data points across all instances of the content from the source component.

Increase process traceability – Identify whether your documentation has been approved, who approved it, and when with the help of content analytics and monitoring. You can also use clear content labeling to highlight critical product data or safety-related warnings that can't be changed.

Greater planning reliability – Create auditable trails for your regulatory submission documentation and share them with regulatory teams. And with a dashboard, analytics and unified reports, your regulatory affairs department can improve planning efforts and share more accurate estimates.

Seamless integration with your eQMS, RIM or EDMS – Seamlessly integrate with the tools you already use to submit documentation to regulatory bodies, streamlining the entire submission process.

Discover how you can streamline your regulatory submissions process 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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