Tridion One

Solutions brief for pharmaceutical and biotechnology

The only solution specifically designed to eliminate legacy documentation risk and future-proof regulatory content with AI-ready approaches to authoring and content management. Built in partnership between RWS content experts and pharmaceutical companies' regulatory documentation specialists.

Overview

Pharmaceutical and biotechnology companies are challenged to deliver therapies to patients more quickly and cost-effectively than ever before. A significant proportion of molecules entering clinical development will fail. Organizations must ensure that a drug's failure is due to its own mechanism of action or its clinical characteristics, and never due to flawed processes or underlying technologies.

Bringing a single molecule to market can cost up to **$4.54B** – before it reaches the patient. Each stage of the process is a race against rising costs, shifting regulations, and relentless competition.

Legacy documentation workflows hinder operational agility, resulting in version creep, manual duplication, and human error. Meanwhile, AI technologies are advancing at a rapid rate. But in a highly regulated market, how do you ensure that AI is not just a buzzword, but a value enabler that helps your organization develop therapies faster and more securely?

Solution

Technology is critical in sustainably accelerating the complete documentation and submission process. Modern, integrated core systems, alongside Regulatory Information Management systems (RIM), enable the controls and data-centricity required to pivot in a rapidly evolving, AI-driven landscape. Crucially, these systems should be built to support optimal processes within the pharmaceutical industry and streamline compliance.

Structured content authoring (SCA) and structured content management (SCM) are key elements in managing documentation at a granular, data level. By breaking documents into reusable, metadata-rich components, Tridion One:

- **Establishes a single source of truth:** Eliminates version creep and ensures all authors work from the same validated content base. Tridion One Templates support content reuse across various regulatory documents and automate content updates using data-driven features like Smart Placeholders and Smart Tables
- **Enables secure, value-driven AI:** Transforms unstructured documents into verified, AI-ready data streams
- **Secures compliance:** Enforces regulatory structure and audit trails by design. Furthermore, conditional content within templates automatically includes or excludes sections based on the specific data requirements of the final document, driving core automation

The frustrations of unproductive systems no longer burden Medical Writers, Clinical Scientists, and Regulatory Specialists; instead, they can refocus on high-value scientific work and accelerate time to market.

Key benefits

Tridion One is an AI-enabled solution specifically designed for the pharmaceutical industry. Streamlining every step of the development lifecycle, it leverages SCA to enable rich data management and facilitate faster and more accurate compliance with FDA, EMA, GxP, and other regulations.

Benefits	Summary
Generate first drafts faster with AI	Slash authoring, review, and approval times by combining pre-approved content reuse with AI-generated first drafts from your LLM.
Collaborate more easily	Enable real-time, multi-user collaboration in an intuitive, familiar editor to efficiently manage even the most complex documents and streamline the entire review cycle.
Improve content consistency and variation control	Maximize efficiency by reusing pre-approved content. Give editors the control to instantly view and selectively propagate content or data changes across applicable templates and documents.
Save time and effort with automated output	Publish effortlessly by generating multiple outputs (Word, PDF, XML, JSON, FHIR) and integrating with connected systems to fuel RIM and AI applications from your single working document.
Meet translation and localization requirements faster and cheaper	Achieve efficient, compliant translation by integrating Tridion One with RWS Trados Enterprise to track content component relationships and automate the push-pull of reviewed content.
Streamline dossier submission	Modularizing the dossier structure allows teams to rapidly create and assemble submissions using reusable, pre-defined templates tailored for specific therapeutic and entity types.
Optimize compliance	Simplify compliance and reduce risk through robust content consistency, precise component-level version control, and comprehensive audit trails.

Use cases

Clinical: Create and update complex documents more efficiently across the clinical development cycle, with granular content reuse and other automations that minimize manual effort and error. From study protocols to operational manuals and clinical study reports, you'll produce more consistent and accurate documents, significantly faster.

Regulatory: Simplify submission preparation and eCTD formats with automated data ingestion, governed content reuse, precise version control, reliable audit trails, and dynamic output from a single source –directly into your RIM system or to any other destination – all of which minimize risk and help you respond faster to regulatory change.

Manufacturing: Transform the creation of critical CMC documentation with sophisticated workflow controls that help stakeholders focus just on their piece of the puzzle in a timely manner. Also, tailor to different local requirements, including translations, with the help of highly automated control of content variations.

Safety: Take the pain out of pharmacovigilance by easily generating PBRERs, RMPs, and aggregate safety reports across the product lifecycle. Customized templates help you fulfil the needs of each document type (e.g., PSUR, DSUR), while the principles of structured content minimize errors and accelerate authoring, review, and approval.

Summary

The integrity of your documentation is the backbone of your dossier and your intellectual property. By adopting Tridion One's structured content platform, you can eliminate the hidden costs of legacy processes, mitigate the new risks posed by uncontrolled AI, and achieve the regulatory controls required to bring life-saving therapies to market sustainably.

See the platform in action: Request your personalized demo of Tridion One and calculate your time-to-market savings.

Learn more

tridion.com/tridion-one

About us

RWS is a global AI solutions company empowering the world's most trusted enterprise AI.

Our proprietary Cultural Intelligence Layer, powered by 250,000 data specialists, cultural and language experts and deep domain professionals, backed by 45+ patents, makes enterprise AI culturally fluent, contextually accurate and secure, ensuring every interaction reflects a brand's tone, context and customer values.

Through our Generate, Transform and Protect segments, we deliver intelligent content, enterprise knowledge, large-scale localization and IP protection for global growth. Trusted by 80+ of the world's top 100 brands, RWS provides the confidence, governance and expertise organizations need to deploy AI safely, responsibly and at scale.

Headquartered in the UK, RWS is listed on AIM (RWS.L).

More information: rws.com

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