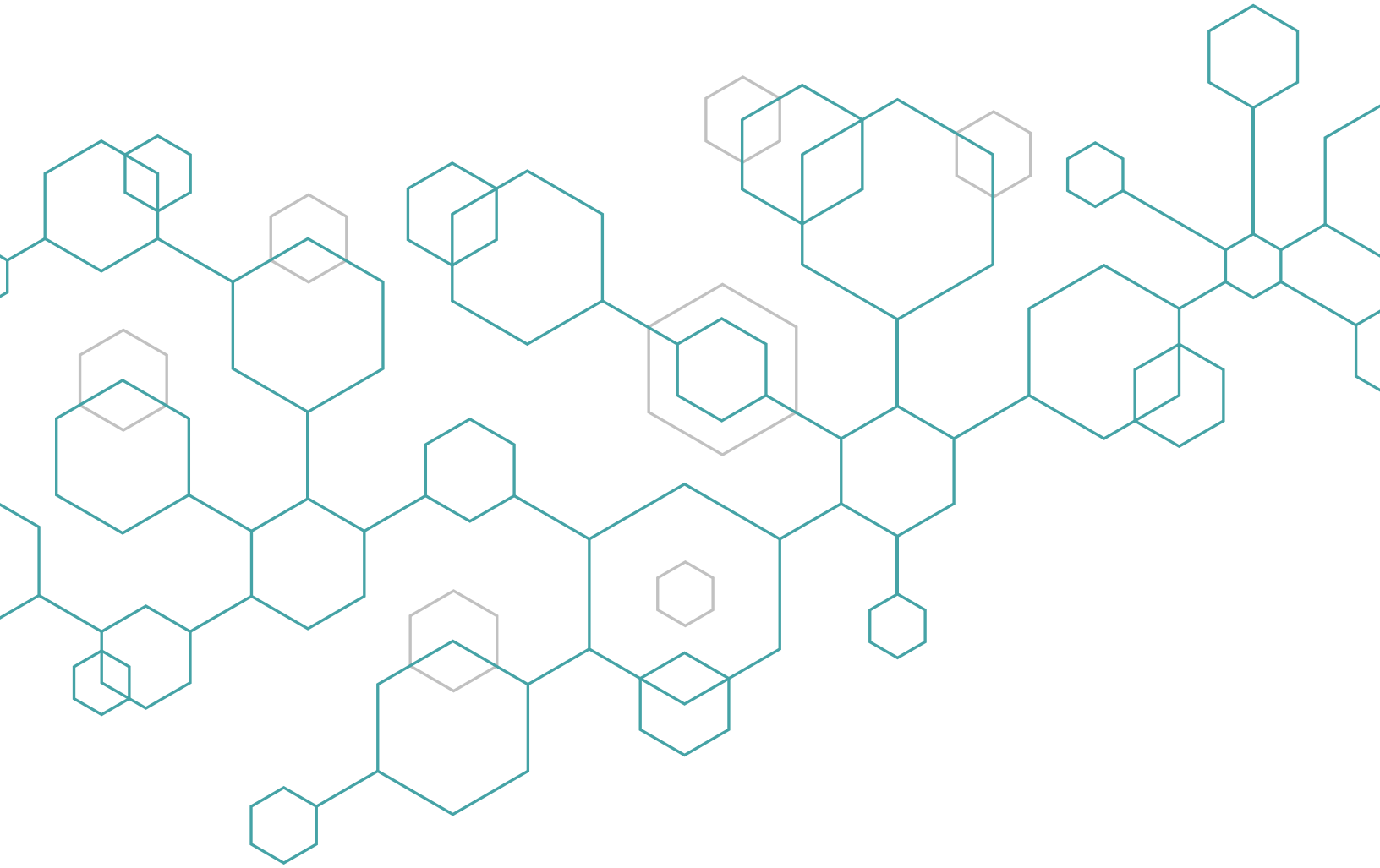
Docuvera™

SCA: The IT-approved Life Sciences solution for content

Discover how structured component authoring can simplify medical information documentation



When choosing documentation software for life sciences, IT professionals must keep security, scalability, reliability, extensibility, ecosystem integration, and compliance in mind. Many solutions on the market cannot meet those requirements. If they do, they are often too complicated for end users.

For life sciences, documentation is complex. When you pair a high volume of authors and reviewers with an extended timespan for complicated projects, one thing becomes clear: organizations need a solution attuned to the industry's nuances. Structured component authoring (SCA) answers the challenges of drug development lifecycle documentation and offers a streamlined documentation workflow — with the capability to reuse approved information to easily create new documents.

Then, why has life sciences been so reluctant to adopt this technology? One answer might lie in IT.

Finding an SCA solution that fits the Life Sciences industry

There's a reason why many organizations have turned to the cloud: resiliency. According to McKinsey, the cloud can offer faster recovery time, more flexibility, and more tools that provide sophisticated resiliency capabilities. *So why the delay in life sciences?*

Challenges with Life Sciences content development

Perhaps the leading reason for resistance to an SCA SaaS product within life sciences is that though solutions exist, most are attempting to cross over from other industries and are not purpose-built specifically for the life sciences. From multiple authors and reviewers working across hundreds of paragraphs and pages, locations, and extended timelines to strict regulations which must be adhered to, calling it complex would be an understatement.

Medical information authoring requires a solution with deep knowledge of the ins and outs of the industry. Switching from a familiar albeit inefficient documentation system of disparate platforms means organizations need a solution that works for the life sciences, is intuitive for users, and is easy on IT for successful implementation and adoption.

How a SaaS SCA solution can enhance security to support medical information authoring

There are many benefits for users of a SaaS SCA solution: efficiency, reduction in errors and omissions, a foundation for digital transformation, and security.

From an IT perspective — where keeping your network secure is a top priority — the last thing you want is software that opens the doors to security breaches resulting in patient and compound/drug related data becoming compromised.

Luckily, there are platforms created to keep your information and users safe. Covering a whole spectrum of preventive and proactive security measures, the right SCA solution gives IT the power to keep your organization safe via:

Spectrum of security measures:

- **Identity and access management**
- **Integration with SSO**
- **Connectivity through SSL/TLS and SFTP**
- **Data encryption in transit and at rest**
- **Software has multiple levels of testing**
- **Security/audit logs**
- **Intrusion prevention**
- **Network architecture controls**
- **Daily system backup plans and disaster recovery plans**
- **Incident management procedures**
- **Static and dynamic vulnerability testing**
- **Comprehensive patch management**
- **Data separation at the application design level**

Reliability, scalability, and extensibility should be included

Whether you are a small operation or a multinational corporation, you need a platform that fits your needs. A cloud-based SaaS solution should easily scale with enterprise deployments, such as with microservice infrastructure and relying on scalable hosting services (e.g., AWS).

Look for SCA platform architecture with high fault tolerance demonstrating 99.99% uptime, as well as microservices infrastructure, global infrastructure with multiple availability zones and failover capabilities, and dynamic monitoring and elastic provisioning of resources.

Extensibility is also not to be overlooked. The life sciences evolve, so your SCA solution should be able to handle a variety of use cases and have a use case configuration layer. With a reliable solution that can be utilized at any stage, from small to enterprise — no matter how the size or needs of your organization fluctuates — you won't need a new provider.

SCA must simplify content authoring while maintaining compliance standards

An SCA solution designed for life sciences will ensure compliance through a comprehensive range of features. A full Quality Management System (QMS) guarantees adherence to rigorous validation and release processes. Incident management capabilities can swiftly address issues, while detailed audit trails provide transparency and traceability. By adopting critical standards such as 21CFR Part11, data integrity, and regulatory compliance are ensured.

Everything you need and nothing that you don't

With many SaaS products, you get one of two things: an amazing project that looks great on the surface but is a mess underneath. Or, you have a product that is an engineer's delight with how it works on the back end but doesn't quite work for the intended user. Many popular solutions have (i) an end-user-friendly experience and (ii) the ability to be integrated easily into other back-end infrastructures You need both.

SCA can deliver a seamless IT integration

When SCA is created to be easily adopted by the end-user, it should also be designed to integrate seamlessly into your IT ecosystem. In life sciences documentation, many systems move content upstream and downstream. Any new software must integrate smoothly with existing infrastructure — if not, it causes unnecessary work for everyone involved.

SCA: Simple for users and IT departments

These days, no one in IT has any bandwidth to onboard new, complicated programs, especially if whatever the organization was using before did an adequate job. Insights from Gartner suggest that one reason so many implementations fail is because IT projects need less complexity.

With simplicity front and center, a well-defined interface can support communication between systems resulting in a cleaner integration. For example, using REST APIs and Enterprise Service Bus, an SCA solution can integrate with upstream systems like metadata management systems and data repositories and with downstream systems like Document Management Systems.

An intuitive SCA platform can solve the common SaaS problem of integrating complex software smoothly within an IT department via:

- **REST API**

  A software architecture that imposes conditions on how an API should work, REST was initially created as a guideline to manage communication on a complex network like the internet.

- **ESB**

  The enterprise service bus (ESB) can monitor events from both platform and external systems and identify specific events on which certain actions should occur. An orchestration layer can then generate actions based on those events within the SCA system or within an external system.

A two-phase integration process sets SCA up for success

Integrations with new systems should be approached in two phases. First, an initial integration analysis and design phase document the technical design required. An execution phase follows this to implement any customization with an interface.

Once a connector is developed for an upstream or downstream system, it can be leveraged for future integrations with incremental customers. Look for a company that has experience with building these connectors.

SCA must speak to upstream systems

For life sciences organizations, "upstream" refers to systems that contain content that will be used within the authoring process (e.g., metadata, statistical data, references, etc.). In this scenario, users can grab content pieces from upstream systems and use them to create documents in the SCA platform.

An SCA platform can integrate with a variety of upstream systems, including:

- **TFL systems**

  Tables, Figures, and Lists (TFL) systems contain raw content that is used in downstream authoring systems.

  For example, a data table on adverse reactions in an upstream TFL system can be pulled into Docuvera and used in the document.

- **NLG systems**

  Natural Language Generation (NLG) systems create text content based on data and other import sources.

  For example, suppose you have a table of adverse reactions that describes the side effects of a drug; NLG will create a paragraph of content that describes the information in the table (saving the author from a monotonous process of writing paragraphs to describe data). SCA can integrate with these systems so content can automatically generate based on data and pushed into the correct part of the document.

- **MDM systems**

  Master Data Management (MDM) systems store the metadata that is used across many systems. By centralizing, you can automatically update with new metadata from the authoritative source.

If SCA can integrate with these systems, you can use the centralized metadata to categorize components and document content.

In addition to upstream content systems, SCA solutions can also integrate with authentication systems, allowing a company to control access and roles within the platform. For example, when a user quits an organization, the IT department can quickly remove access to critical systems instead of going into each system to manage access and permissions.

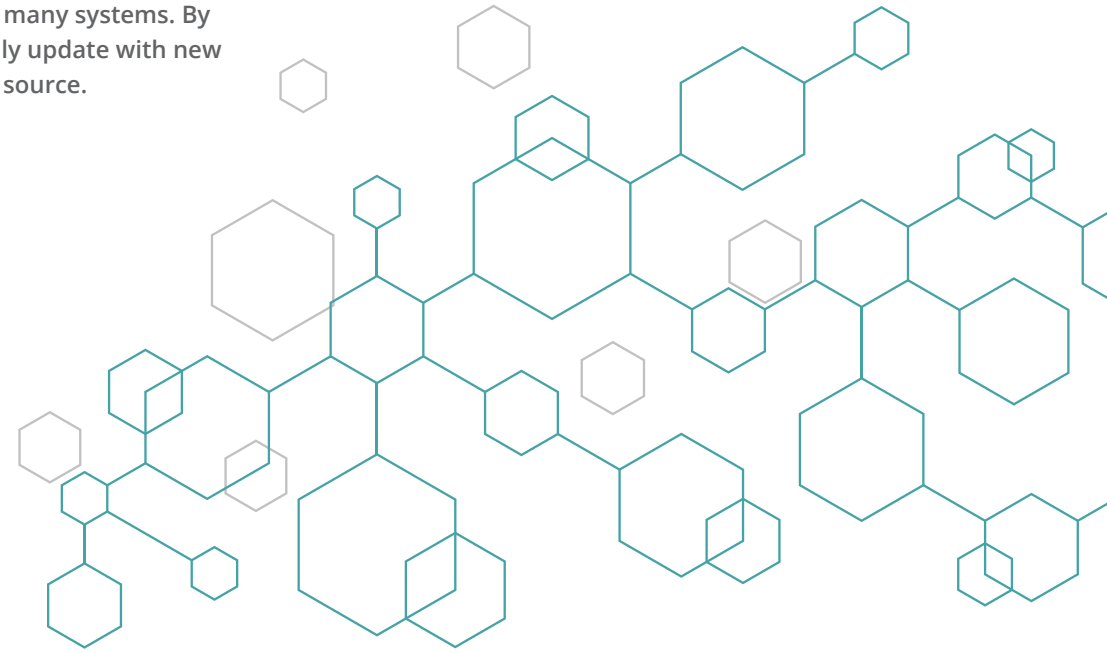
- **SSO systems**

  Similar to IAM systems, these systems can authenticate users into the platform with credentials that a pharma IT department manages, enabling them to quickly turn off access to a downstream system if necessary.

- **IAM systems**

  Identity and Access Management (IAM) systems oversee users and their access levels to various downstream systems. By enabling IT with the capability to centrally control users' permissions across internal and third-party systems, they can better manage how these systems are used to limit potential security breaches.

Ensure your choice of SCA solution supports fine grained access control, which allows the system to host data with different access requirements to 'live' in the same storage space without running into security or compliance issues.



Downstream systems? Ensure your SCA is ready

Once you have approved content for life sciences organizations, there are many “downstream” applications for your finalized documents. Your SCA solution should be designed with these considerations.

DMS systems

Document Management Systems (DMS) store the source of truth binary files. SCA should integrates with these systems, so the final binary files that are created can be pushed into those systems.

Translation service providers

SCA can integrate with translation service providers so documents can be exported from the system, translated, and imported back into the platform, all while maintaining relationships with the source content.

Web frameworks display content as web pages

Integrating with your SCA platform allows for HTML documents or components of content to be pushed downstream into these frameworks so the content can be displayed on the web pages.

Chatbots

Similar to web frameworks, components of content from within the SCA platform can be pushed downstream into chatbot flows. A user asking questions via a chatbot workflow can receive answers recorded in the same document.

IT can breathe easier with SCA designed for simple implementation

These days, IT has a full workload. From keeping your organization online and secure to troubleshooting everything technical under the sun, many departments don’t have time to add one more variable. When an SCA solution is designed for both the user and IT, it can be easily rolled out with minimal work required from your valuable IT resources.

After ecosystem integration considerations

Sure, adding a new solution to the tech stack is one thing, but what happens after you've integrated the SaaS service, gotten everyone signed in, and started using the tool? How can you ensure that your data is safe? How can the service adapt as your organization grows or experiences reduction? What if you want to expand the use of the application to other functional areas? Is there additional support available from the vendor?

From protecting proprietary knowledge to evolving to function for the demands of your organization, you need a smart solution that works with you — not against you.

You shouldn't have to go it alone

IT departments are busy. When selecting an SCA vendor, ensure your solution is paired with comprehensive support to assist you through every step of your implementation. From planning, training, integration, and deployment, to ongoing support post-launch, a true partner will provide post-integration care options to ensure that authors are comfortable with and can utilize the full spectrum of capabilities of the solution.

Docuvera: SCA designed for a Life Sciences tech ecosystem

If you are a life sciences organization, chances are you're not just working on labeling or clinical documentation. You need a solution that functions for cross-channel applications. Because Docuvera can be configured for different document templates, workflows, and permissions sets, our SCA solution can work across departments in one extensive ecosystem.

To deliver maximum value, Docuvera does three things: it is easy to use, secure, and can easily integrate into existing infrastructure. If you want icing on the cake, Docuvera is accompanied by implementation assistance, onboarding guidance, and ongoing, top-tier support.

Docuvera's SCA solution is the only product on the market that pairs an intuitive interface and back-end with the security and support required for medical publishing — all in a platform specifically created for the life sciences industry.

Example of a typical implementation

Scenario: A Global Biopharma Company (GBC) has been searching for a solution to streamline its documentation process.

Their requirements:

- Simple interface that requires minimal training to start using
- Easily scalable across different functional areas
- Minimal impact on an already busy IT department
- On-demand support that doesn't go away once the final check is in the mail

Madelyn, who has sat in many meetings with leadership and IT, discovers Docuvera while browsing for options. After reaching out for a demo, she was pleasantly surprised at the quickness of response and the ease of use of the platform. After sharing a case study, GBC decides to move forward with Docuvera.

The onboarding process is as follows:

1. A demo is shown to a group of people from the organization: leadership, IT, authors, managers, reviewers, etc.
2. A small group gets access to a trial version to try out the platform.
3. Docuvera suggests an implementation plan that includes timing, change management communication, training, and more.
4. The organization rolls out Docuvera first to a group of champions who undergo training and deliver feedback to help set up the solution to best work for GBC.
5. Client-based configurations are made before rolling out to more users.
6. Meanwhile, the organization has been primed for this new tool that will soon be available.
7. Finally, it's launch day! Docuvera is rolled out to all designated users, with on-demand support available.
8. After a predetermined amount of time, Docuvera and project leads check in to ensure smooth implementation and make any necessary adjustments.

For life sciences, the challenge of SCA has always boiled down to needing a simple experience for the end users with a back-end that requires minimal IT integration, upkeep, or maintenance efforts, all in one product.

Docuvera is an integrated, cloud-based structured component authoring (SCA) solution that allows organizations to create, share, and manage regulatory documents more efficiently. Developed by ASC, a world leader in component-based authoring solutions, Docuvera was explicitly designed to focus on the needs of the life sciences industry. By combining familiar interfaces with innovative technology solutions and databases, Docuvera brings consistency and greater compliance to the life sciences documentation process. Visit docuvera.com to learn more.

Docuvera™

info@docuvera.com • 1-888-999-1021