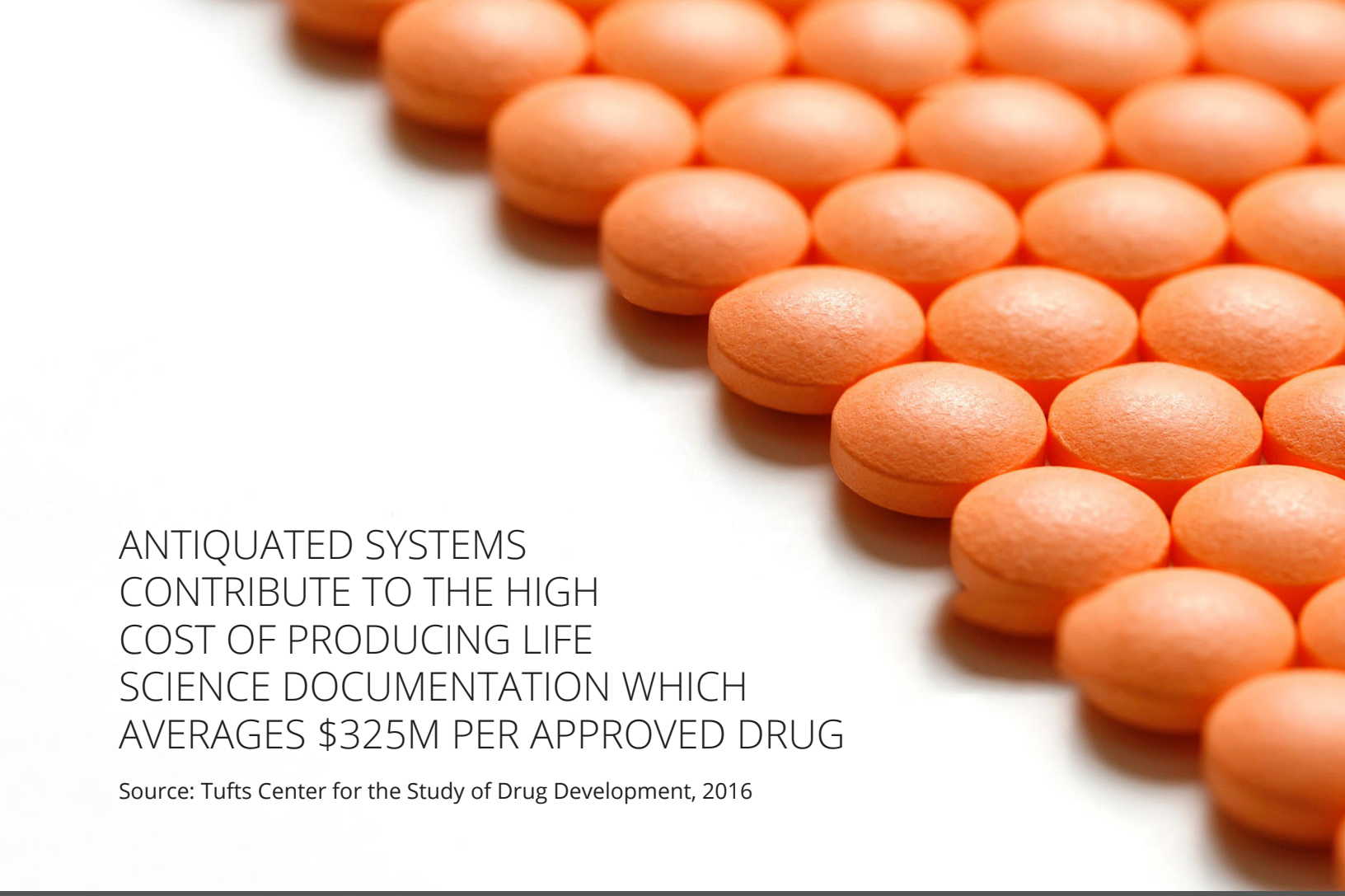
REALIZING THE PROMISE OF STRUCTURED COMPONENT AUTHORING

This white paper explains how the adoption of structured component authoring can dramatically improve the efficiency, accuracy, transparency and speed of creating and updating Life Science documents.

Docuvera



ANTIQUATED SYSTEMS CONTRIBUTE TO THE HIGH COST OF PRODUCING LIFE SCIENCE DOCUMENTATION WHICH AVERAGES $325M PER APPROVED DRUG

Source: Tufts Center for the Study of Drug Development, 2016

It's time to address the inefficiencies with using desktop software to create and update Life Science documentation, but it's challenging to find a solution that's easily adopted by medical authors who are accustomed to creating documents using Word.

The Life Sciences industry struggles with inefficiencies, human errors, low visibility and the high costs of managing information. Structured Component Authoring (SCA) provides an alternative to these inefficient processes, allowing reuse of approved components of content to assemble documents. Changes to these components efficiently propagate to everywhere the component is reused. There are a range of SCA solutions to consider, and careful evaluation is needed to select a solution that can drive the maximum adoption for your organization. With the right solution, your company can double productivity, reduce compliance risk, avoid expensive expansions in staff, and generate substantial ROIs.

THE PROBLEM

Word is grossly inadequate as a tool for pharmaceutical documentation.

Using Word to author pharmaceutical documentation is common, but its shortcomings are obvious – essentially, information in a document is trapped, where it is difficult to find and cumbersome to repurpose. Many documents often reuse the same content, and searching for and cutting and pasting paragraphs is a notoriously inefficient way to create a document. If an update is needed, the author must manually find and edit the copy across the entire suite of documents. In addition to the inefficiencies, the possibility for errors and omissions is enormous, risking significant rework, fines and work stoppages by health authorities.

In addition to the inefficiencies and errors rooted in copying and pasting, additional shortcomings of desktop publishing include:

- No collaboration features are prevalent in SaaS solutions, so only one author can work on a document at a time
- Difficult to enforce a common look and feel for documents, and style changes are cumbersome as content changes; content reuse is also complicated by style and structure variances
- No workflow capability to allow documents to be routed through a series of authoring, review and approval stages
- Translating content is more expensive, as entire documents will require re-translation rather than just the modified components
- Word documents cannot be easily repurposed into other formats (e.g., HTML, XML, chatbots)
- No built-in audit trail
- Impossible to link metadata to specific content, an evolving requirement for data submissions (e.g., IDMP)

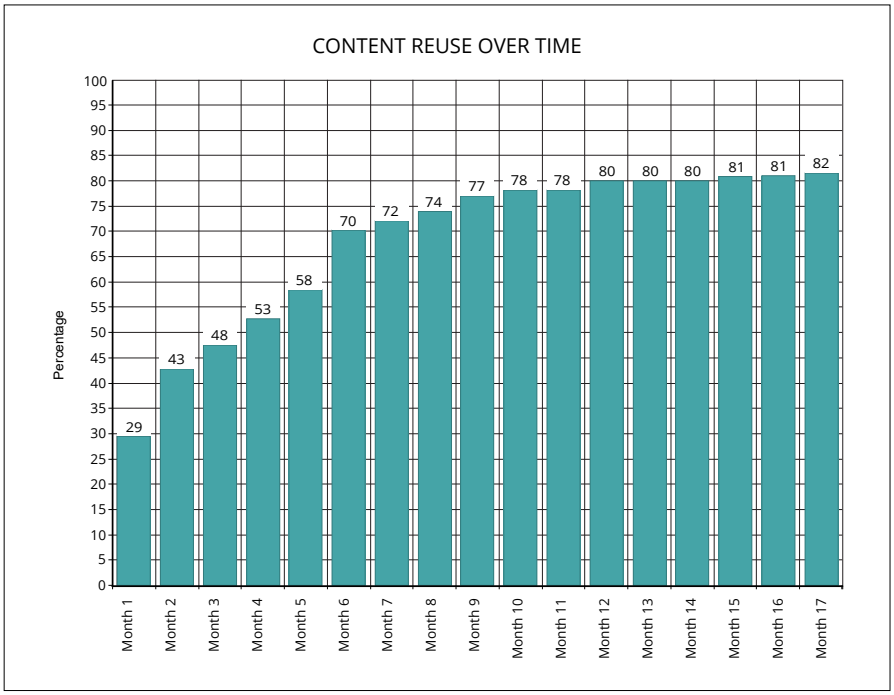
THE SOLUTION

Structured Component Authoring

When effectively implemented, SCA dramatically improves the efficiency, accuracy, transparency, and speed of creating and updating Life Science documents. Through SCA, pre-approved blocks of content can be reused in many documents. Instead of thinking about creating new content, authors focus on assembling documents based on these approved content components. When changes are made to a block of content, the changes propagate everywhere that information is used.

In addition to reusing component content, templates and formats for many kinds of documents can be built once and used many times. For example, a clinical protocol template can include the structure, styling (e.g., headings, paragraph text, table text, etc.), and metadata for the protocol. The template approach to SCA reduces the need for authors to worry about the latest structure, formatting and metadata that needs to be associated with their documents. And, because styling of documents is controlled by stylesheets at the template level, the same content can be used to produce Word, PDF, HTML, XML and other document outputs.

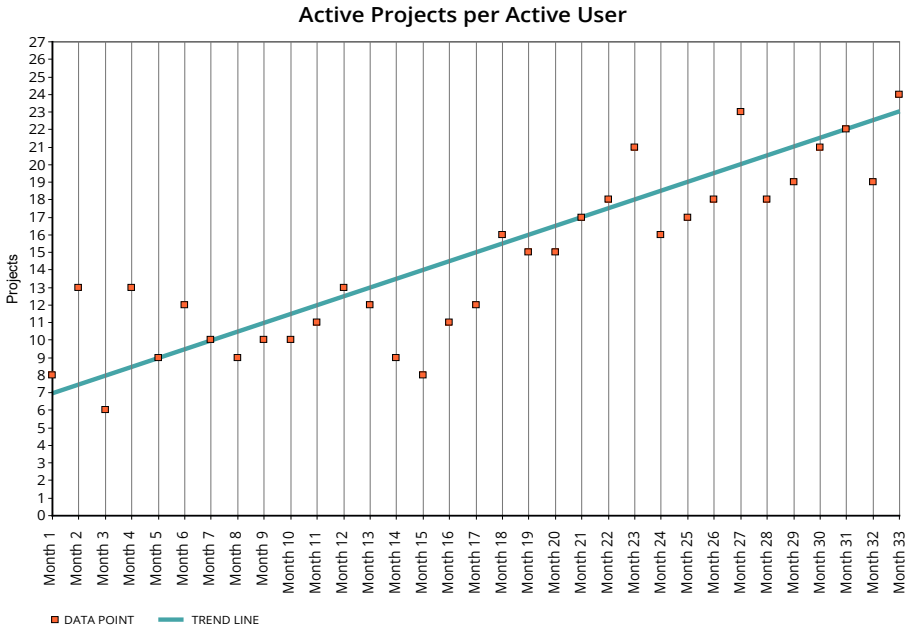
Structured component authoring takes collaboration to a new level, allowing multiple authors to work on the same document simultaneously without the need to coordinate who is making changes to the master document. Even with multiple users updating a document simultaneously, the system keeps detailed, real-time audit records of individual content additions, edits, deletions, and comments, while approved document versions are locked and stored in a system archive for audit purposes. Collaborative reviews create a single forum for discussions and resolutions with key stakeholders. Workflows, including reviews, approvals, and exports, are clearly delineated and help guide a document through the various stages of development.



This chart from a typical customer shows the percentage of content reused over time when SCA was adopted. In a little less than three years, content reuse jumped from 29% to 82%, with the biggest jumps taking place in the first year.

SPECIFICALLY, SCA BENEFITS INCLUDE:

- **Less Time Creating Content:** Documents can be assembled from pre-approved components. Within local documents, component content can be reused as-is, or, modified while still maintaining its relationship with the source component.
- **Less Time Updating Content and Fixing Errors and Omissions:** Reused content efficiently propagates to local documents. If an important change is made in a component that is reused, the authors of local documents that reused the modified component are notified that an update is available. Local authors can decide to update their content, make modifications based on source changes, or choose not to make any changes.
- **Less Time Collaborating on Documents:** Rather than a check in/out method, SCA creates a collaborative editing environment with multiple authors that includes a simple audit trail. So, it is easy to see which author made changes, and when the changes were made.
- **Less Time Styling Content:** Styling individual documents for consistency is labor intensive and time-consuming. With SCA, document formatting is created once in a stylesheet and automatically applied to all relevant documents. If modifications are desired, changes to the stylesheet will automatically update all documents using that stylesheet. Documents become much more consistent in style, no matter how many authors work on them.
- **Less Time Setting up Document Structures and Metadata Properties:** Templates defining document structures and associated metadata can be built once and used over and over. Authors can be assured they are using the latest document structure and metadata by selecting the appropriate template.
- **Reduction in Errors and Omissions:** The risk for errors and omissions is dramatically reduced through SCA because pre-approved components of content are reused without the risk of accidental modification. Approved components are locked and clearly identified as approved, while new or modified components are highlighted as draft components that need to go through an approval process.
- **Facilitated Alignment with Regulatory Requirements as the Industry Moves toward Digital Submissions:** SCA assists in the alignment with new standards such as the Identification of Medicinal Products (IDMP) which helps companies remain compliance with the evolving requirements for digital submissions.



In this chart from a typical customer, the increase in number of active projects per active user is documented.

CHOOSING THE RIGHT SOLUTION FOR YOU

The different types of SCA solutions each have their benefits and drawbacks.

TRADITIONAL XML SOLUTIONS

XML SCA solutions have been around for decades. Typically found in more traditional industries (e.g., aerospace, high tech manufacturing), these solutions are used to produce documents like technical manuals. Because tech writers in these industries are dedicated to producing documentation full-time, these solutions tend to be feature rich with many options to produce high fidelity outputs. However, XML solutions are generally more difficult to use because, as with most software, ease-of-use is inversely proportional to software features. In Life Sciences, authors are more familiar with the simplicity of Word, so gaining adoption with the more technical XML solutions can be challenging. Further, these solutions tend to be more fragmented and require complex integrations of various functional modules (an editor from one company, a search engine from another one, a database from a third, a publishing engine from a fourth). Integrating multiple functional components increases implementation risk and long-term maintenance costs.

WORD ADD-IN SOLUTIONS

Another class of SCA tools are Word add-in solutions. These applications benefit from using Word as the primary editor for creating content, thereby providing a level of familiarity for Life Science authors who have long created documentation in Word. However, integrating SCA functionality within the Word interface can be kludgy. For example, reusing content from both component libraries and existing documents is cumbersome in side panels, while managing workflows can require plug-ins and check-in/out processes. Collaborating simultaneously on the same document is not possible in the desktop software, and restricting functionality in the Word interface can be confusing for authors who are used to building exactly the content they want.

WEB-BASED SAAS SOLUTIONS

A new breed of web-based SCA systems address a lot of the traditional issues with XML and Word-macros solutions. Their interfaces are built to focus on assembling documents using components, but with the simplicity of modern text editors like Word. Being web based, they can allow users to collaborate on the same documents simultaneously, avoiding the complicated check-in/out processes required with traditional document systems. They can also combine non-authoring functions like review and approval, publishing, and audit trails that are not typically embedded in traditional systems. However, because these systems are newer, they may lack all the bells and whistles of the traditional systems, thus limiting the amount of customization desired by some IT departments.

BEST PRACTICES FOR ADOPTING A SOLUTION

Selecting the right solution is one of the key steps in realizing the promise of SCA. The efficiencies gained from SCA can only be achieved if the solution is widely adopted across the organization's use cases and the enterprise as a whole. For maximum return on investment, authors must embrace the solution not because they've been asked to, but because it genuinely makes their jobs easier and faster.

When evaluating SCA solutions, things to consider are:

- **Ease of Use:** Most life science users have been writing pharmaceutical content in Word for years if not decades, so having a SCA system that feels familiar to Word users is an important part of user adoption. There are many examples of medical authors rejecting complicated solutions that force them to think more like software programmers than authors, so make sure ease of use is highly considered when evaluating different options.
- **Level of System Integration for SCA:** Having fewer functional modules to integrate into a complete SCA system lowers implementation risk and ongoing maintenance costs. Integrating editors, workflow engines, publishing engines, etc. may deliver a more tailored solution, but implementation risks and costs will increase. Systems that bundle these core functions on a single platform will lower costs and risk by elevating system changes to a configuration level (versus code level changes).
- **Self-Service Configuration Flexibility:** Having an SCA system that can support a wide variety of use cases (e.g., clinical, regulatory, medical, safety, CMC, etc.) through application configurations creates the opportunity for enterprise-wide deployments and content reuse across the entire drug development lifecycle. By support different use cases at the application configuration level, a single SCA service to be deployed to different teams within an organization without having to provision additional services and/or work with the software provider to update their code. And, having this configuration layer as part of an admin console will allow an enterprise to modify configurations as desired versus being locked into the software provider to update application configurations.
- **Ecosystem Integration:** Being able to integrate within a larger IT ecosystem is critical to minimizing changes to complementary systems and processes while benefitting from layering SCA across those elements. As a result, an SCA system should have well-developed interface technologies and methodologies (REST APIs, Enterprise Service Bus layers).
- **Security:** Security is a critical evaluation criteria for any IT system. An SCA solution should provide strong identity and access management (SSO integration), data encryption both at-rest and in-transit, security and audit logs, intrusion prevention and detection, network architecture controls, system backups and disaster plans, incident management procedures, and many more considerations. Security audits should be performed for any vendor before moving forward with a partnership.

- **Scalability:** An SCA solution should be scalable to support an enterprise-wide deployment for thousands of users. When evaluating a SCA solution, a review of the solution architecture is critical (e.g., Is the SCA based on microservices architecture allowing for different components of a service to be scaled on demand? Is the SCA solution hosted in AWS or Azure allowing for exponential scaling?)
- **Reliability:** An SCA solution should be architected to sustain potential adverse IT events (e.g., Does the SCA offer a fault-tolerant architecture where services are isolated via a microservices architecture? Does the SCA leverage service providers like AWS or Azure with multiple reliability zones and the ability to failover across these data centers?)
- **Compliance:** An SCA solution should simplify compliance and quality management through validation and release processes, incident management capabilities, and audit trails (e.g., . Does the SCA service align to ISO standards ISO/IEC 27001, SO/IEC 20000-1 and ISO 9001:2015, EU GMP Annex 11 – Computerized Systems, 21 CFR Part 11, etc.?)
- **Audit Trail:** For an SCA system, having a detailed audit trail of content changes, workflows, and other events can be an important part of an overall compliance footprint. In addition, consider whether an SCA service has content alignment reporting that shows when content has been modified from the source and deviation reporting that documents why content has been modified in meaning or emphasis.
- **Training and Support:** Adequate training and support is a critical consideration when choosing a SCA solution. Make sure a SCA solution includes implementation training as well as a hypercare period where any identified issues can be quickly diagnosed and resolved.
- **Proven Engagement Model:** In addition to the SCA solution characteristics, it is also critical to follow an adoption plan that minimizes the risks in transition to a new technology. Steps in that plan should include:
  - Early evaluation of content reuse to understand the potential of SCA to drive efficiencies (SCA should only be considered if there is high reuse among documents)
  - Review of business processes and organizational readiness for SCA
  - Building a plan to organize content assets for optimal efficiencies within a SCA solution
  - Several rounds of prototyping of a SCA solution with evaluations by medical authors
  - Assembling a governance strategy to ensure the implementation stays on course with the proper level of leadership support
- **Use of Legacy Content:** Being able to use legacy content is critical to achieving a fast return on investment while providing a familiar content framework from which authors can adopt a SCA solution. When exploring SCA, make sure to have a strategy to assess content, design and architecture that breaks down legacy content into a logical organization, and migrate that content into the SCA solution. This ensures that many years of content can be migrated seamlessly, and immediately be reused to assemble new documents.
- **References:** Before moving forward with any SCA solution, make sure to check the Life Science references of the vendor being considered. References within other industries are riskier as the characteristics of Life Science companies are different from those of more traditional SCA markets. The SCA solution should have solid examples of implementations within specific Life Science use cases that demonstrate high adoption (hundreds of users), strong reuse (70-80%), and significant ROIs (>100%).

CONCLUSION: SCA WILL TRANSFORM HOW YOU DO BUSINESS

When implemented effectively, SCA will slash the time needed to create documentation, dramatically increasing output without having to add staff members – making a major improvement to the bottom line.

82% Content Reuse Drives New Levels of Efficiency

With SCA, companies have been able to achieve high levels of reuse of existing, approved content – thus eliminating the need to create/ review/approve/translate redundant content.

Efficiency Improvements Lead to 110% Productivity Gains

Improved efficiencies allow existing teams to take on more initiatives without adding staff. A typical customer has more than doubled the number of documents they manage.

Productivity Gains Drives 12 Month Break Even

With SCA systems that generate broad productivity gains while achieving widespread adoption, companies reach rapid breakeven of initial investment in implementation and services costs.

Productivity Improvements Build a Strong Business Case

During their initial rollout where 50 users doubled their productivity, a typical customer achieved a NPV of $3.2MM and a 145% ROI as users devoted the time saved to new products (and thus avoided increasing personnel costs to take on those new projects). The financial benefits will only increase with wider adoption and new use cases.