

Structured Content Authoring by Fonto Made Accessible in Your Business Application

Three Life Sciences R&D Use Cases



The future of documents is shaped by a fundamental change in how information is shared. This future sees a shift from traditional »e-paper«, formatted and optimized for reading by humans, towards semantically tagged information in an open digital format. Regulatory submissions are still very much centered around »classic« documents: formatted PDFs. The common practice is to write in Word, and copy and paste data manually, then take a »picture« of that document by creating a PDF version which is submitted. This intrinsically poses risks of inconsistencies, and the inefficiency of the practice is increasingly problematic. While documents are accompanied by structured XML for key-data and meta-data, documents and data are still »separate worlds«. Structured content authoring has the potential to bridge them together. Structured documents are component-based, contain included data and are largely created automatically.

Fonto provides an XML editor to let subject matter experts create, edit and review mission-critical documents – flawlessly, fast and efficiently. It brings structured authoring, editing and review capabilities to authoring solutions. It is configurable for any document-type, is web-based and can easily be implemented in any authoring workflow.

Business users need to have efficient and effective access to data and documents no matter where it originated or where it is finally stored, addressing Clinical, Regulatory or Quality needs. It is fundamental to not look at structured content authoring in an isolated way but to provide an integrated approach for end users, enabling access to all core functionality through their primary business application.

integration-center from fme provides a cloud-ready and pre-configured integration framework, allowing for faster and easier integration of implementations across all the major platforms, including Veeva Vault, OpenText Documentum, Generis CARA, and many others.

Structured Content Authoring (SCA)



Fonto

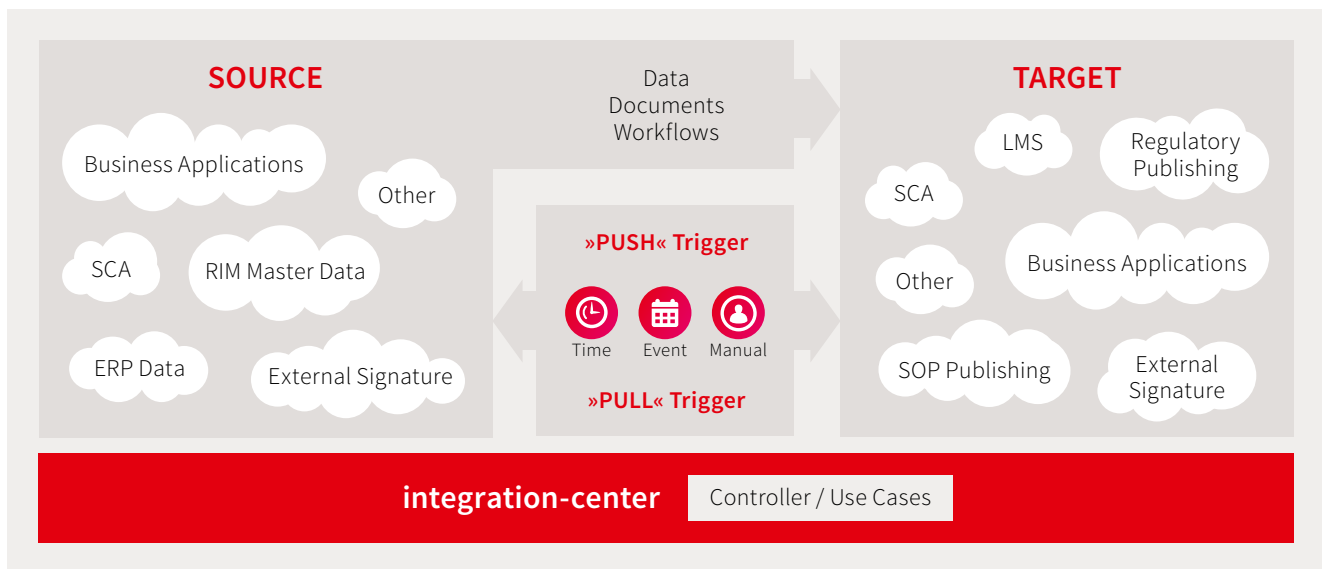
Structured Content is content which is not formatted for a single outputted form but is reusable and versatile. By adopting structured content authoring, organizations get ready for the following:

Document automation | Data-driven, automated generation of documents from content components allows for efficient production of mission-critical documents.

Collaborative authoring and review | Collaboration, review and approval workflows based on content components allow efficient collaborative content creation and precise control over content quality.

Digital and data-driven publishing | In a future where formatted documents are replaced by digital forms of content and data exchange, structured and semantically tagged content bridges the gap between documents and data.

More information on Fonto: www.fontoxml.com



Get your business applications connected

The integration-center framework allows robust and flexible connections between systems in your enterprise landscape. A wide range of use cases can be covered in and around our core partner platforms and their externalized APIs.

Structured Content Authoring (SCA) Use Cases

Let's have a look at where the SCA integration between Fonto and your business application such as the Veeva Vault suite can help your business users across the pharmaceutical domains.

Clinical

In the Clinical area, SCA can help with the consistent reuse of content across studies, addressing synopsis documents, protocols and study reports. A big part of the CTD package is contributed from the Clinical business functions, including clinical study reports in Module 5 and clinical summaries and clinical overview documents in Module 2. Specifically, looking at Module 5, clinical study protocols, statistical analysis plans and the compiled clinical study reports are very data-intensive, with data constantly changing, and can benefit significantly from content reuse and automation – leading to reduced risks and faster turn-around times which are critical in submission processes.

Allowing business users to use SCA, enabled by Fonto, for example from their Veeva Clinical business application, will enable them to leverage these advantages as part of their day-to-day work from a single user interface.

Global Labeling

All marketed drugs and devices have associated product labeling information that must be provided according to regional requirements. Maintaining this labeling information worldwide is a complex process. The core product information is duplicated for dissemination across thousands of documents.

Using an SCA solution such as Fonto provides consistent reuse of content across Company Core Datasheet (CCDS), Company Core Safety Information (CCSI), Summary of Product Characteristics (SmPC) and United States Prescribing Information (USPI).

Accessing these functionalities directly for example from their Veeva Submissions business application enables label managers to achieve significant time savings when assembling labelling documents from reusable content elements that have already been reviewed and approved and facilitates rapid responses to agency requests and changes.

R&D Quality

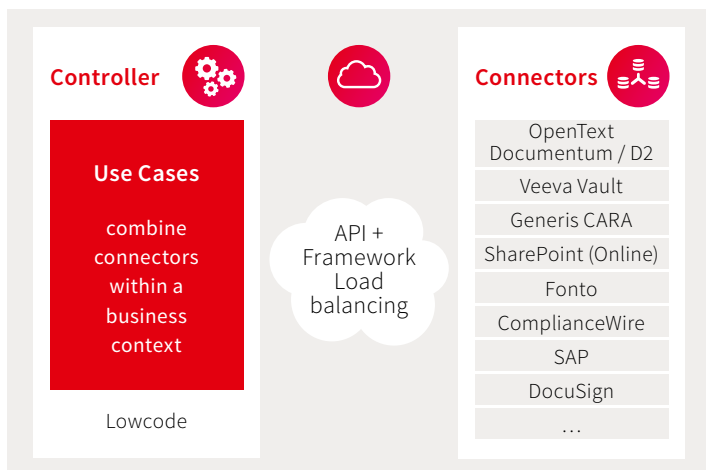
The information contained within the CMC modules of a CTD submission is highly repetitive and heavily data driven, and therefore, represents a prime candidate for SCA. The CMC data in Module 3 is extremely interconnected and dispersed into separate packages as needed. These separate submission packages account for region-specific requirements, revisions based on health authority information requests, new product presentations, and amendments throughout the product lifecycle. This requires significant tracking, knowledge, and effort to ensure accurate and updated information is submitted to each health authority in each separate package.

Utilizing SCA allows users to create, capture, and reuse information as product and process development progresses, addressing the manual and repetitive challenges associated with constructing Module 3 content. It offers consistency and traceability of information across integrated data sets and reduces the manual efforts of accurately reusing data across documents and data sources. Several documents, including drug substance or product specifications can be built from SCA templates from metadata – requiring no human intervention. This reduces the risk of error and provides rapid document creation and approval.

Giving this ability to business users directly through their business application such as Veeva Submissions will additionally contribute to the efficiencies in the process of managing the Module 3 documents.

Build on future-proof technology

Our integration-center connectors for leading business applications, which are implemented as cloud-ready Micro-Services, provide core functionality to read and write data and content and to access and trigger additional processes in these applications as needed. A low code platform provides the ability to realize the actual business use cases by providing business logic while combining the connectors within the business context (controller).



Take advantage of the benefits

- Efficiency – Create components once and reuse through standardised content libraries
- Accuracy – Implement change inside and across documents
- Automation – Remove repetitive manual data collection steps
- Synchronization – Propagate content changes rapidly and consistently in all related documents
- Reduced time and cost – Achieve faster document compilation for long term cost savings
- Improved quality and standardization – Promote consistency across your enterprise

Our end-to-end implementation approach

Implementing integrations within the enterprise landscape is a key component of fme's standard end-to-end implementation approach – from early Business Consulting, through Analysis and Design, Implementation, Testing (specifically Test Plan creation and execution) and Rollout support.

To implement SCA more efficiently, a set of accelerators are leveraged that provide a proven baseline for the integration. These include configurations and supporting documentation to quickly deploy the integration elements. The enablement of any necessary additional configurations in support of the specific use cases, or any frontend changes and trigger points, are performed by our team of technicians who are trained and certified in the leading business platforms Veeva Vault, OpenText Documentum and Generis CARA.

In addition to the technical aspects of SCA implementations, the Business Consulting Services team at fme provides accelerators in the definition of the data model to enable data element reuse, assists in the redefinition of supporting business processes and assists with the successful adoption of the solution through training and change management services.

Get closer to one connected landscape

Tell us your business needs and our team of experts will be happy to help you identify and define how SCA integrations can help you with your path forward – to get closer to one connected landscape!

fme Life Sciences is a leading provider of business and technology services supporting the deployment of Content Services and ECM solutions to its clients in the Life Sciences Industry. We act as trusted advisors and systems integration specialists across the Clinical, Regulatory and Quality and Manufacturing domains in Europe and North America. We do not exclusively recommend or promote any platform or vendor, but rather focus on providing our clients with an independent perspective of the solutions available in the market.