



CARA

Structured Content (component-based) Authoring

Use simple tools for a complex use case



What is Structured Content Authoring

Traditional documents are a “black box” with fixed content. Structured authoring allows a document to be built from individual components such as words, sentences or other such blocks, dynamically, and re-usably



Option 1: using MS Word

CARA allows you to use MS Word functionality to build each component block, and then assemble them into a document structure. On opening, you edit a single large Word document which is saved back as components



Option 2: using metadata components and PDF

Alternatively, individual blocks can be metadata objects containing the name of the block, the text and/or other information, which CARA then dynamically renders to PDF for review and approval



Option 3: integration with third party tools

If neither of the above options meet your requirements, CARA supports integration of multiple third party editing tools (XML or other formats) while handling the assembly of the components and their reuse in the repository

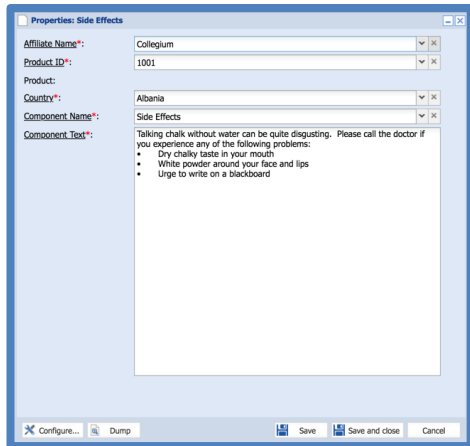


Versioning and “Where used”

Individual components can be versioned in different assemblies, with the ability to visualize the complex version tree graphically in CARA, as well as trace where each component is used and thus the impact of changes to it

The options for Structured Authoring in CARA

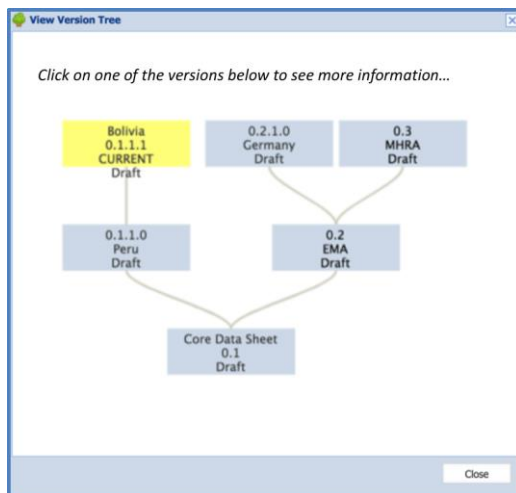
How it works



Create your individual components as metadata objects with both the text and also formatting information, or create them as individual Word documents which can be as little as a single word or image. The metadata of the components, and the editing screens, are fully configurable using the standard CARA configuration tools

Assemble the components into a logical structure using our CARA Structures / virtual documents

| Document name | Version labels | Binding |
|-----------------------------------------------------|----------------|---------|
| Label with PDF concatenate from metadata components | 1.1, CURRENT | |
| <input type="checkbox"/> Active Ingredient | 1.0, CURRENT | |
| <input type="checkbox"/> Dosage Form | 1.0, CURRENT | |
| <input type="checkbox"/> Dosage Strength | 1.0, CURRENT | |
| <input type="checkbox"/> Side Effects | 1.0, CURRENT | |
| <input type="checkbox"/> Manufacturer Name | 1.0, CURRENT | |
| <input type="checkbox"/> Manufacturer Address | 1.0, CURRENT | |



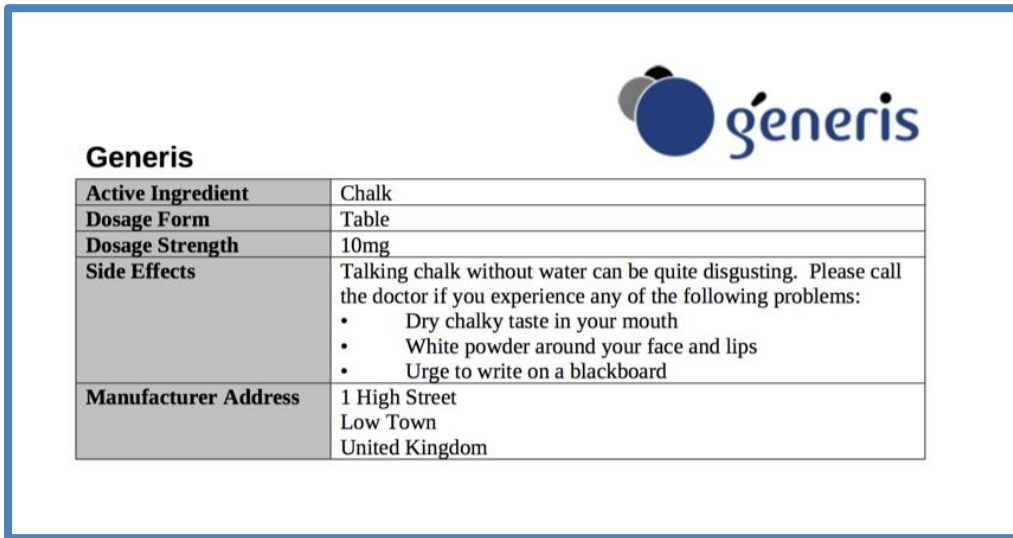
Once the components are in use in different assemblies, they can be independently versioned and bound into other assemblies, while a graphical view shows the history of the versions and how they are derived. Users can also get notified when a core component from which they have derived a version is changed, in case it impacts the derived version



The options for Structured Authoring in CARA

How it works

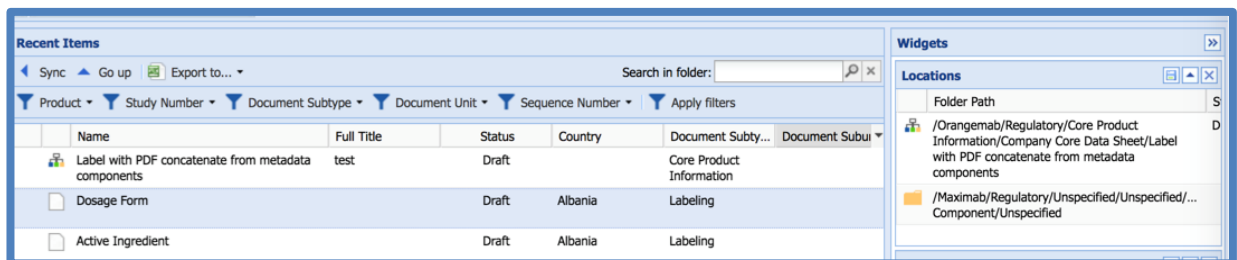
Once your components are built, then either use our Word Concatenation feature or our PDF generation feature to create the compiled content for review / editing – if you edit a Word concatenation then on checkin all the individual modified components are updated



The screenshot displays the Generis logo at the top right. Below it is a table with the following data:

| Active Ingredient | Chalk |
|----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Dosage Form | Tablet |
| Dosage Strength | 10mg |
| Side Effects | Talking chalk without water can be quite disgusting. Please call the doctor if you experience any of the following problems: <ul style="list-style-type: none">• Dry chalky taste in your mouth• White powder around your face and lips• Urge to write on a blackboard |
| Manufacturer Address | 1 High Street Low Town United Kingdom |

Our widgets provide a list of "where used" for each version of each component, allowing traceability to individual compiled documents, and giving the possibility of assessing the impact of changes. Other widgets can track the status of the compiled output in other systems



The screenshot shows the 'Recent Items' table and the 'Widgets' panel. The 'Recent Items' table has the following data:

| Name | Full Title | Status | Country | Document Subty... | Document Subui |
|-----------------------------------------------------|------------|--------|---------|--------------------------|----------------|
| Label with PDF concatenate from metadata components | test | Draft | | Core Product Information | |
| Dosage Form | | Draft | Albania | Labeling | |
| Active Ingredient | | Draft | Albania | Labeling | |

The 'Widgets' panel shows a list of 'Locations' with folder paths:

- /Orangemab/Regulatory/Core Product Information/Company Core Data Sheet/Label with PDF concatenate from metadata components
- /Maximab/Regulatory/Unspecified/Unspecified/... Component/Unspecified



An overview of CARA

Key Features

Personalization

Everyone works in different ways – so users in CARA are able to make choices and changes to the way CARA looks and works for them, and these are saved automatically and used wherever the user logs in, including mobile.

Flexible Navigation

Users can build their own navigation tree (“Dimensions”), choosing what each level maps to. Admins can set up more complex queries to display as navigable trees (“SnapLists”) – e.g. “Show me my department’s documents which expire in 30, 60, 90 days”.

Widgets

One-click display of information about a document – choose from core set (e.g. properties, workflows, thumbnails) or create your own, linking in any web service as a widget e.g. information from another system. See multiple at once, and personalize them with drag & drop.

Different views for different users

Define different views for different user groups / usage scenarios. Specify different properties, widgets, filters, colours, searches and other options, allowing users to work in the way that best supports their processes.

Key Features

Simplified User Experiences

Not all users need all features; have occasional users login directly to a single Inbox view, or a company SOP search portal, or an external contributor upload site, through simple configuration.

Dashboards / Reports

Don’t let your metadata go to waste – use it for reporting on project progress, metrics, and more. Show the results as tables, charts or graphs, and export it all to Excel.

Extending core features

CARA provides access to all the core features of the underlying system, while offering extensions and improvements to many of them, for example virtual documents and workflows.

Fully Configurable AND Customizable

CARA has a rich set of configurations, which allows setup of use cases from SOPs to Media Marketing to Government or Engineering systems. But CARA can also be fully customized – add any menu item, custom screen and define the processing (queries, API, server method, RESTful web service, JavaScript), but package it in our unique “Configurable Customization” wrapper to ensure future upgradeability without re-coding.

Top 20 Life Science company implements CARA across the enterprise e.g. SOP / Quality, through Regulatory Correspondence, Pharmacovigilance to Archiving and Labeling

Global television network uses CARA for managing its marketing information, tracking pricing of products at competitors and dashboarding the efficiency of the time-to-broadcast process

Use Cases

CARA was selected by a global insurance company to provide the end user interface on top of Documentum for managing claims and promotional materials documentation

Top 5 global Life Science company selected CARA as an enterprise wide tool, e.g. Regulatory Submissions documents, SOPs / GxP documentation and Legal Affairs

