# Structured Content Management: Leveraging Automation to Support Authoring Your Global Labeling for Pharma and Device Products

## Pharma Packaging and Labeling Innovation Forum

September 14th, 2023

# Agenda

- Authoring Process Overview
- Issues and Challenges
- Artificial Intelligence Technologies
- Capabilities Available Today





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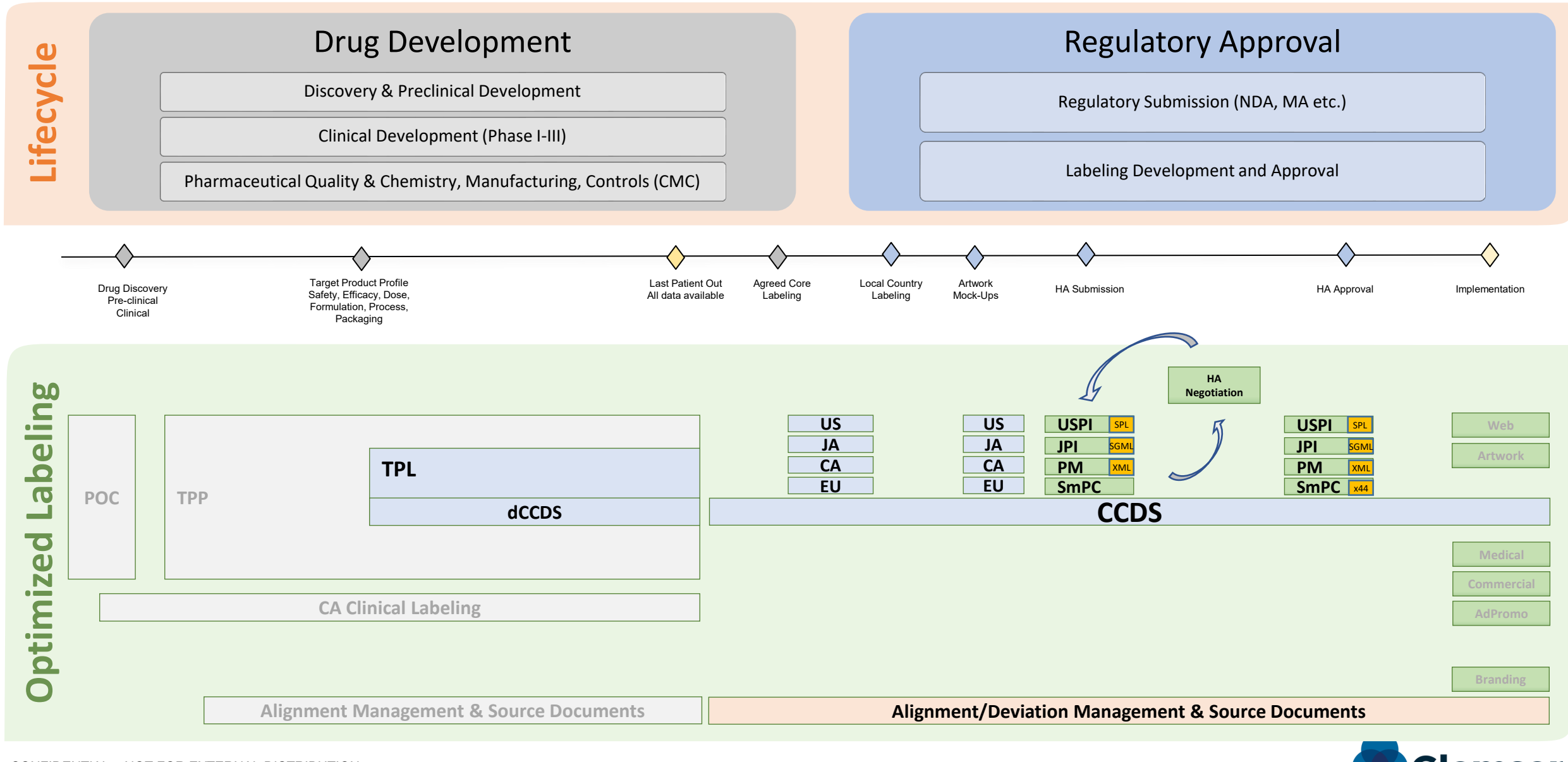
# Efficient Authoring Process for Multiple Country Labeling





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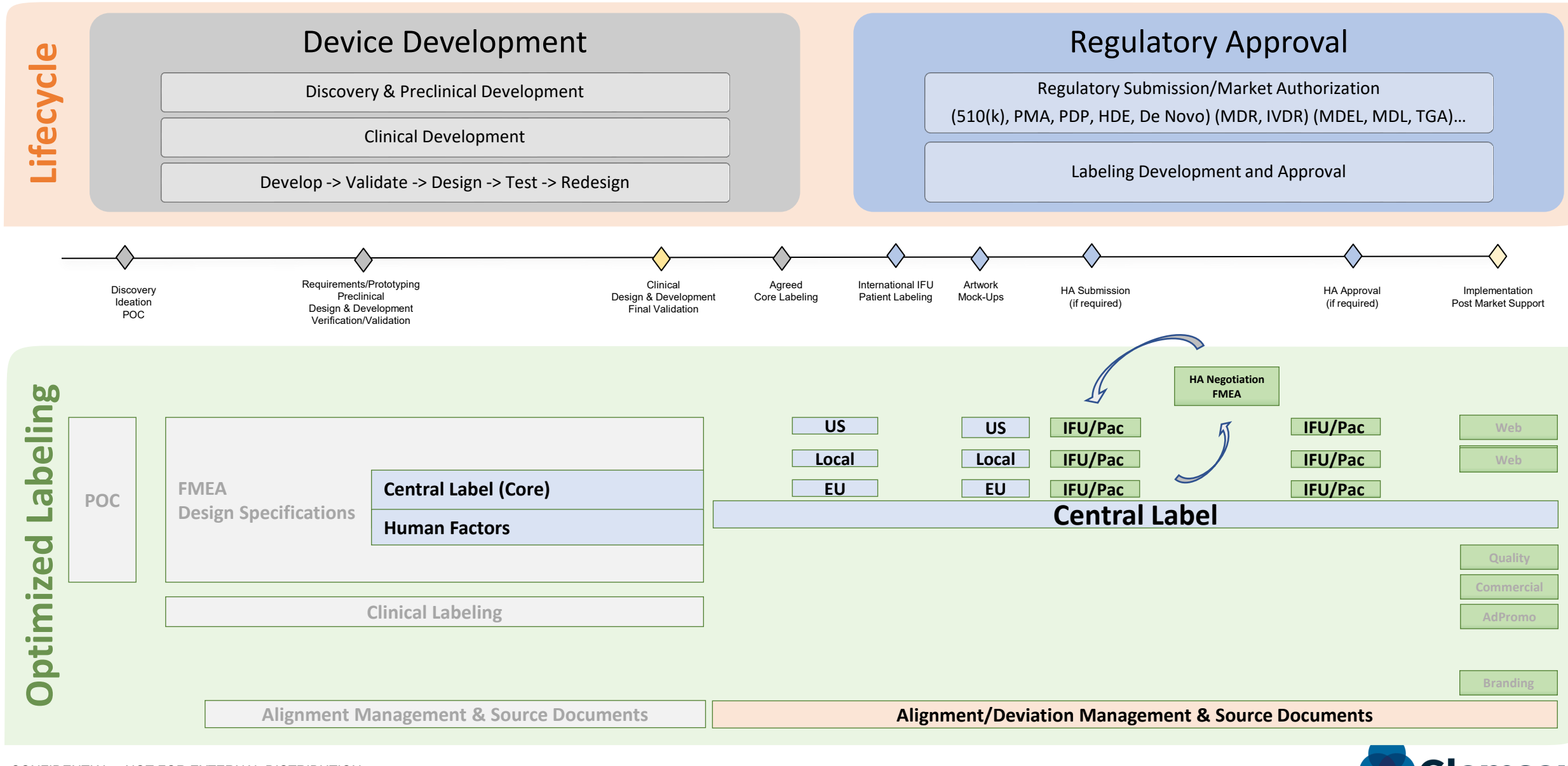
# Efficient Authoring Process for Multiple Country Labeling





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# Global Labeling Processes and Systems Challenges


- The average global label can take up to 13 months to complete, from creation to approval.
- Over the course of that 13 months are hundreds of people working together
- Disparate systems and manual processes puts every organization at risk of increase cost, decreased quality, non-compliance, and wasted time





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# Quantifying Global Labeling Challenges

## Time

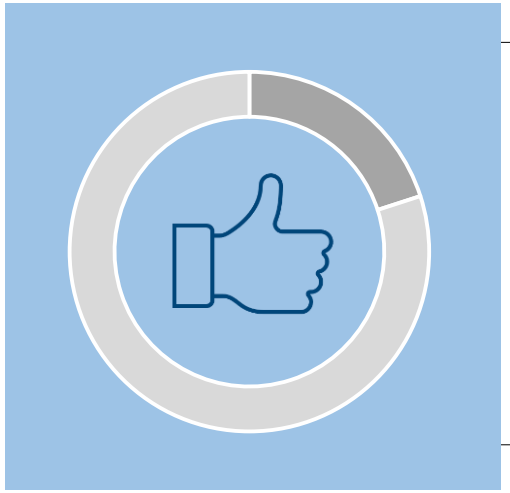
- Labeling changes number in the tens of thousands (30K) over the course of a year
- Complex changes require 12+ months

## Cost

- Translation expenses are in the millions annually
- Lost revenue due to product delays result in losses of $500K annually or more

## Quality

- Emerging standards (FHIR, IDMP, etc.) that require automation systems and tools to fulfill requirements



## Compliance

- Volume of data and changes in documents requires automation in the process to keep labels current and compliant





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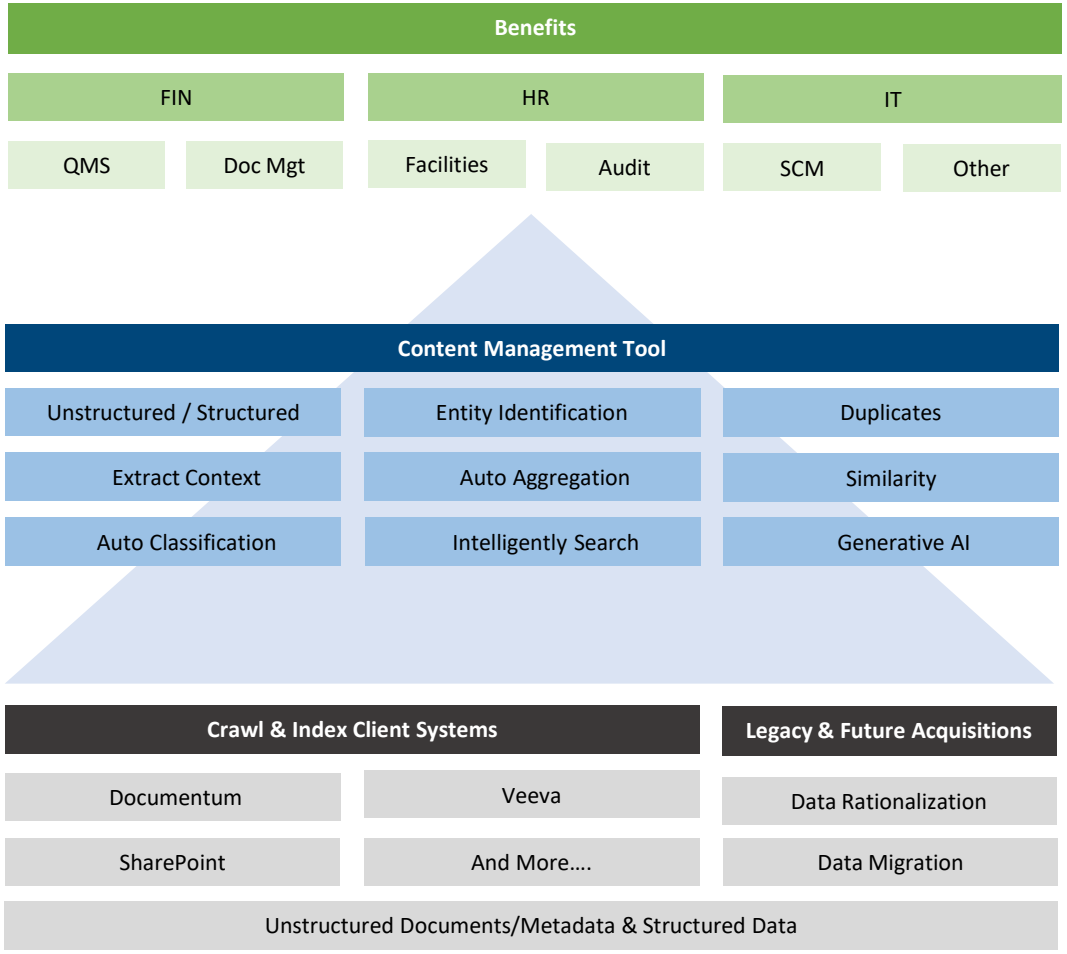
# Artificial Intelligence: Natural Language Technologies

An intelligent search and analytics platform that allows companies to crawl and analyze both unstructured and structured data regardless of where it is stored.




## Intelligent Industry Insights

### Machine Learning
Leveraging machines to analyze unstructured data with industry specific focus that improve over time

### Natural Language Processing
Use machines to read and interpret unstructured data like a human.

### Speech Recognition
Easily convert video, audio and live speech to a text readable transcription

### Computer Vision
Using machines to analyze images or video frames and predict visible entities

### Deep Learning
Deep indexing analysis of unstructured data to help decision making

### Augmented Analytics
Intelligence and entity recognition to create business intelligence from unstructured data with real-time translations





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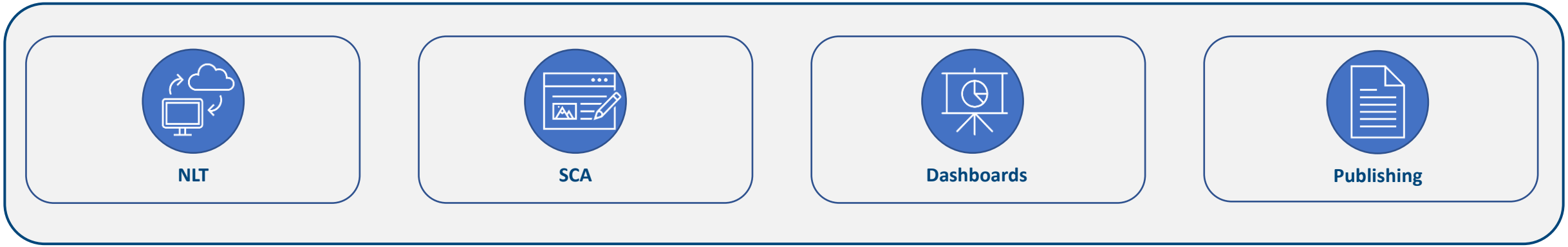
# Capabilities of a Modernized Application

What capabilities should you look for to optimize regulatory content generation.




- Natural language processing and generation models trained on life sciences data
- Automate the most time-intensive steps in your authoring workflow – from cutting and pasting to rewriting to translations

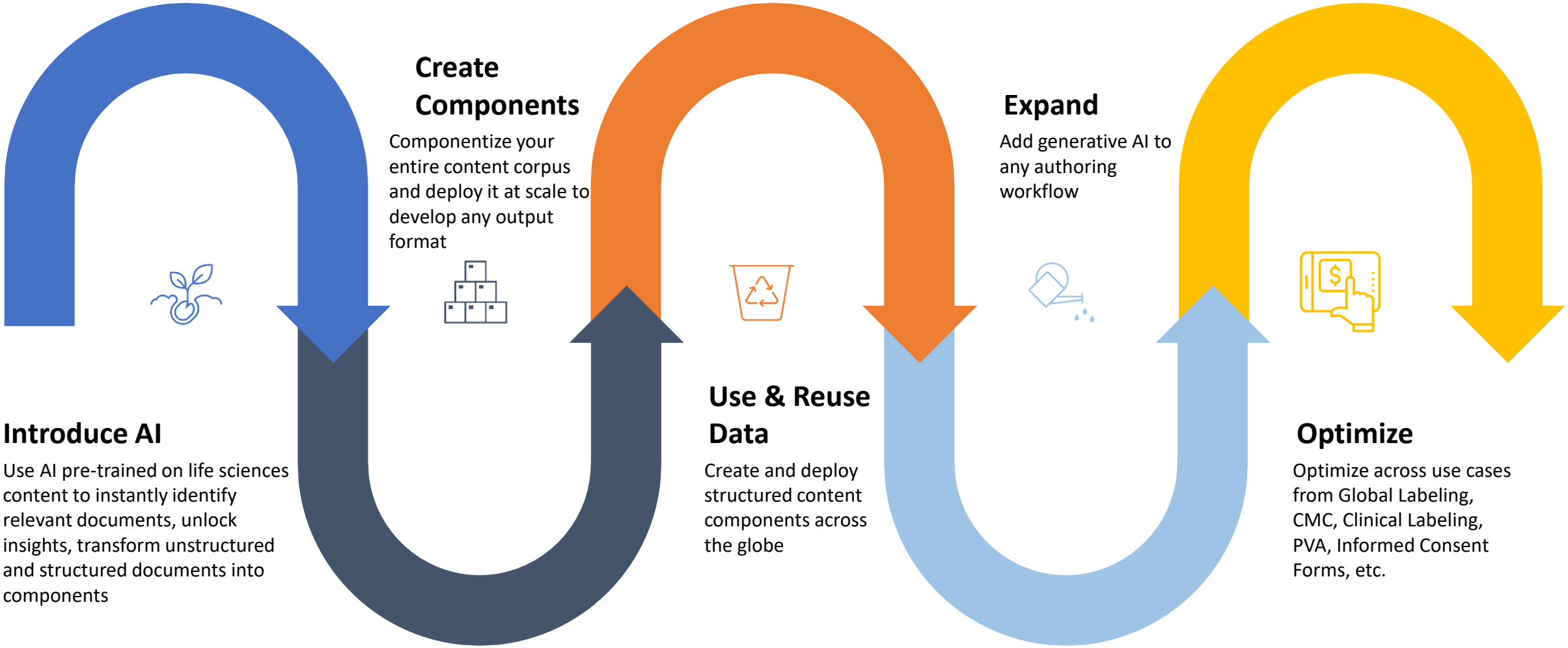
- As you generate, review, and approve content on the front end, ComplianceAuthor™ continuously maintains everything as components on the back end
- No coding or manual conversion necessary

- Review real-time status and timelines via dashboards and reports
- Proactive management to adhere to regulatory and internal timelines

- Using natural language models, structured content authoring software, and dedicated life sciences experts, reduce the structured content management lifecycle by up to 50%

# Automation Journey Map to Optimize Global Labeling

Automation with a human-in-the-loop will optimize your processes.



## Introduce AI

Use AI pre-trained on life sciences content to instantly identify relevant documents, unlock insights, transform unstructured and structured documents into components

## Create Components

Componentize your entire content corpus and deploy it at scale to develop any output format

## Use & Reuse Data

Create and deploy structured content components across the globe

## Expand

Add generative AI to any authoring workflow

## Optimize

Optimize across use cases from Global Labeling, CMC, Clinical Labeling, PVA, Informed Consent Forms, etc.





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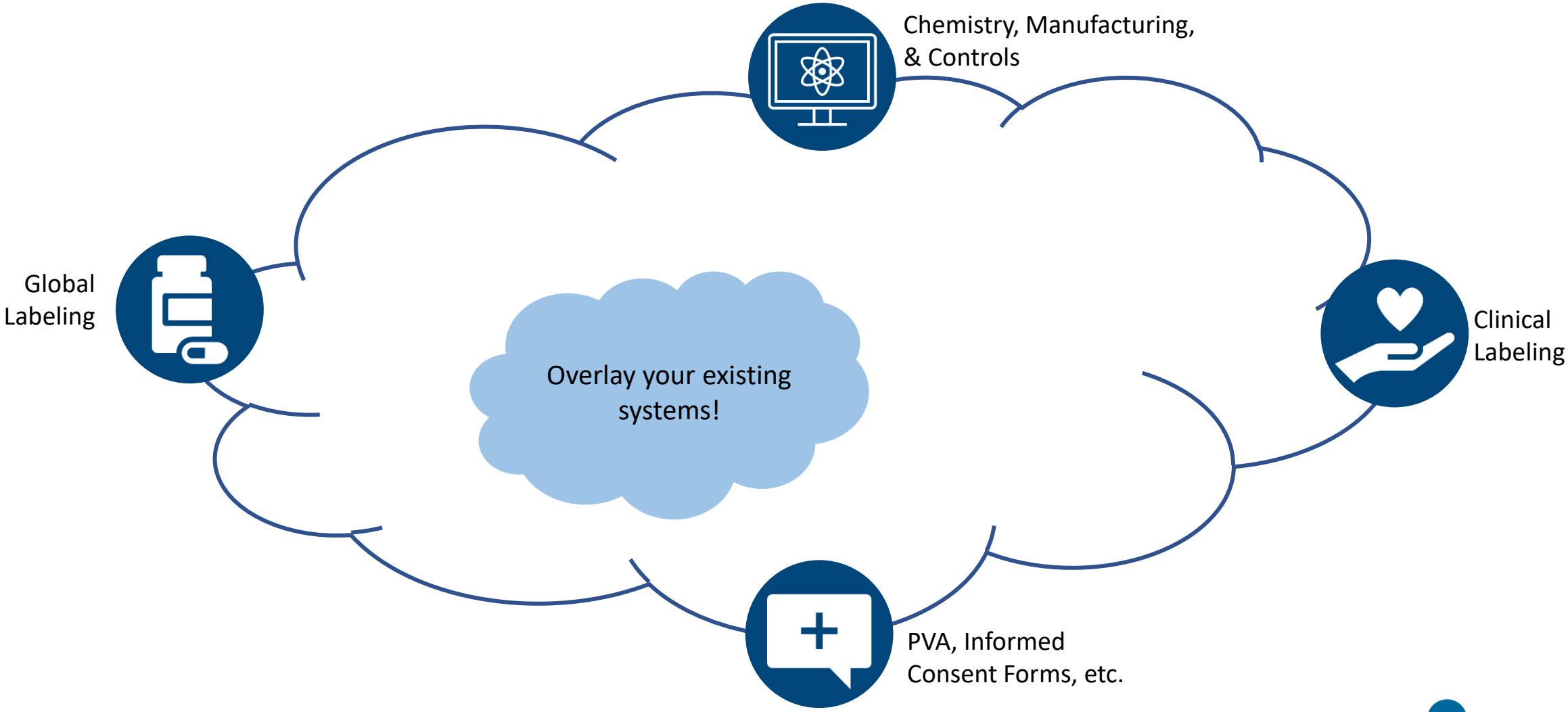
# Organizations Require an Overlay System

Leverage data in your current systems by overlaying your content management over them.





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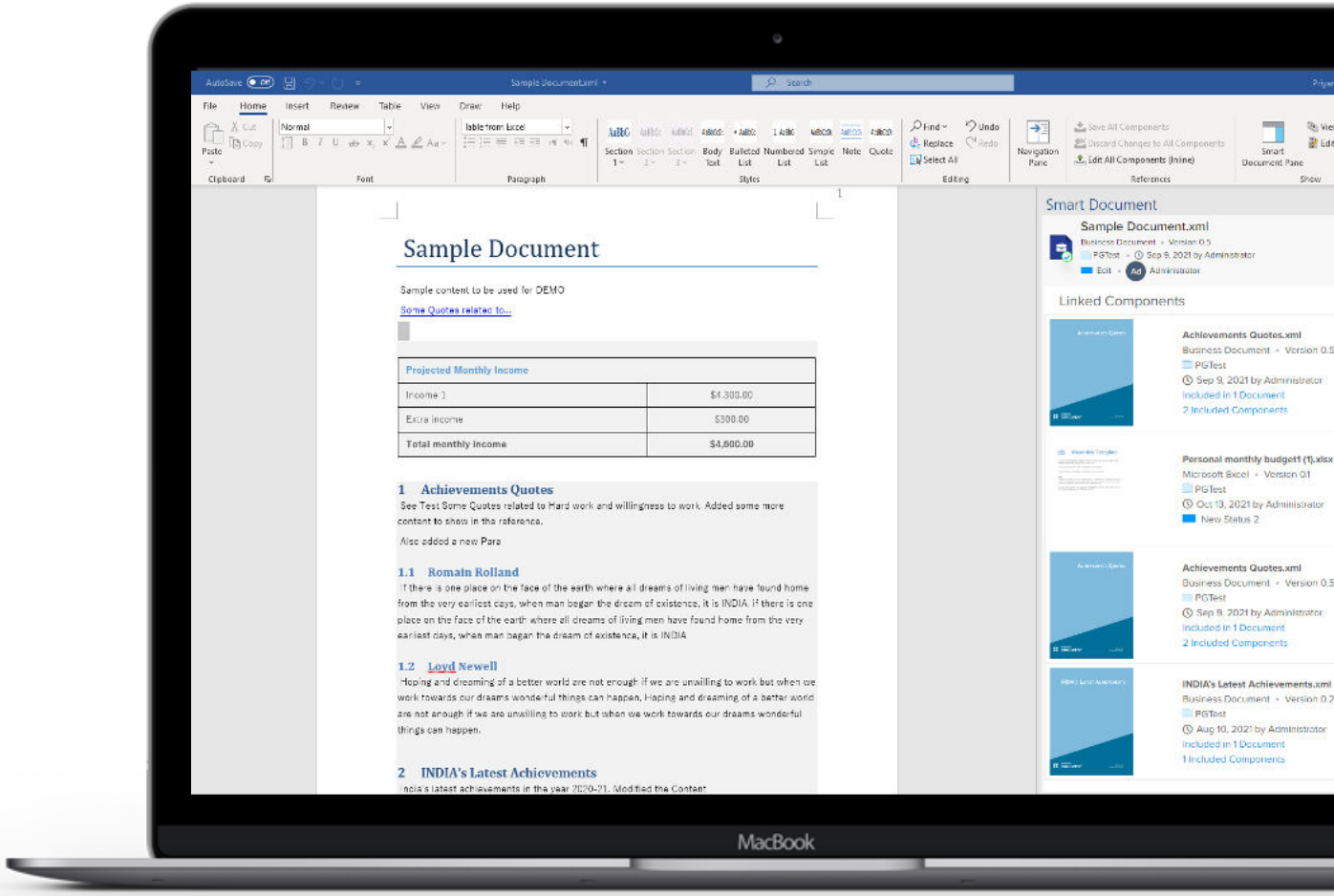
# How might this look like for you?

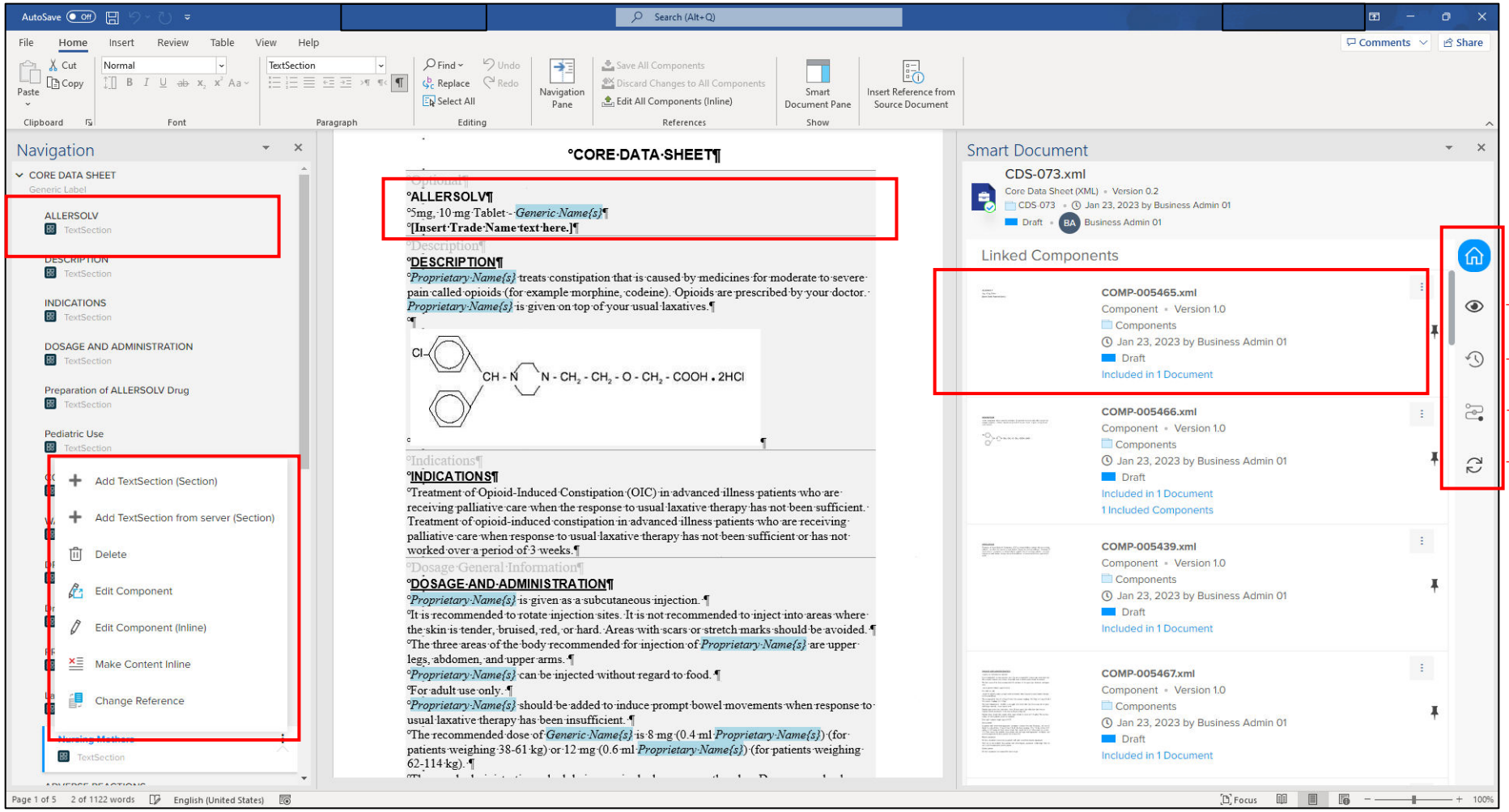
## Structured Content Authoring and Component Management

- Familiar Microsoft Word interface via plug-in
- Direct metadata tagging
- Automatic XML generation, No XML expertise needed
- Life sciences extensions (CFR Part 11, e-Signatures, etc.)
- Modular, componentized authoring and assembly
- Structured Component Management (SCM) processes for tracking, managing and reusing components
- Placement of components in central server for reuse
- Centralized Component Content Management System (CCMS) cloud repository, SaaS model
- Granular integrations of authoring processes and data sources
- Collaborative, parallel review processes from inside MS Word with automatic merging of feedback



# Leverage content in different documents

Consistency across products in formatting and content saves countless hours in formatting.



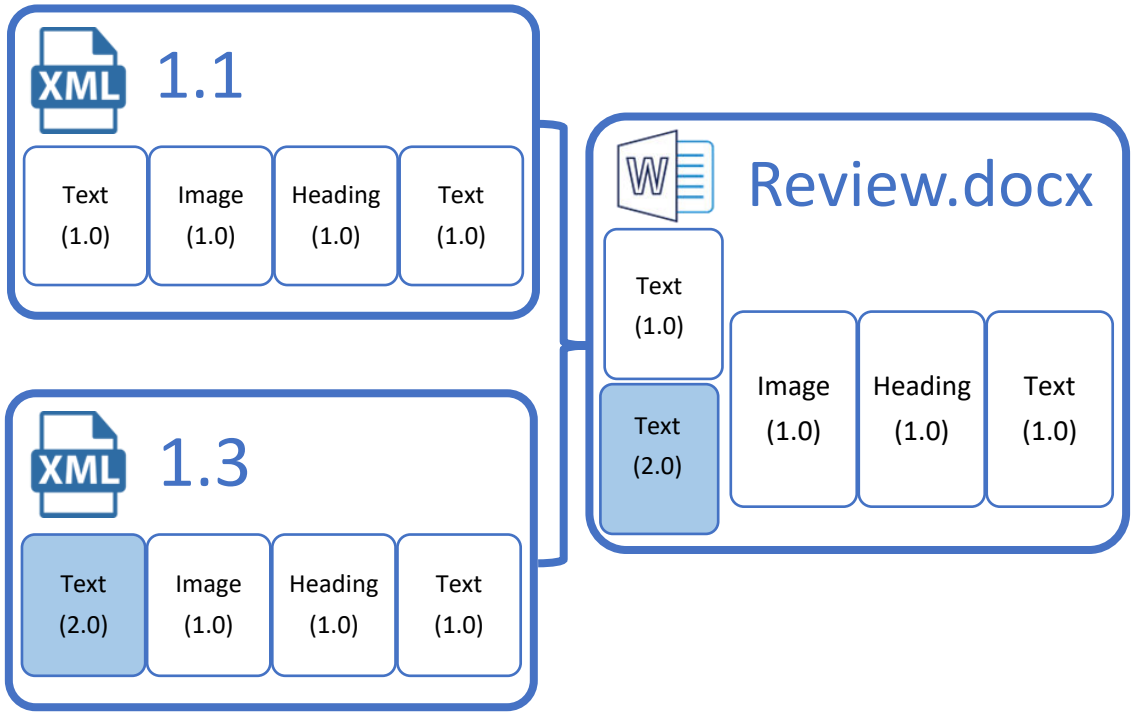

## Smart Pane Menu

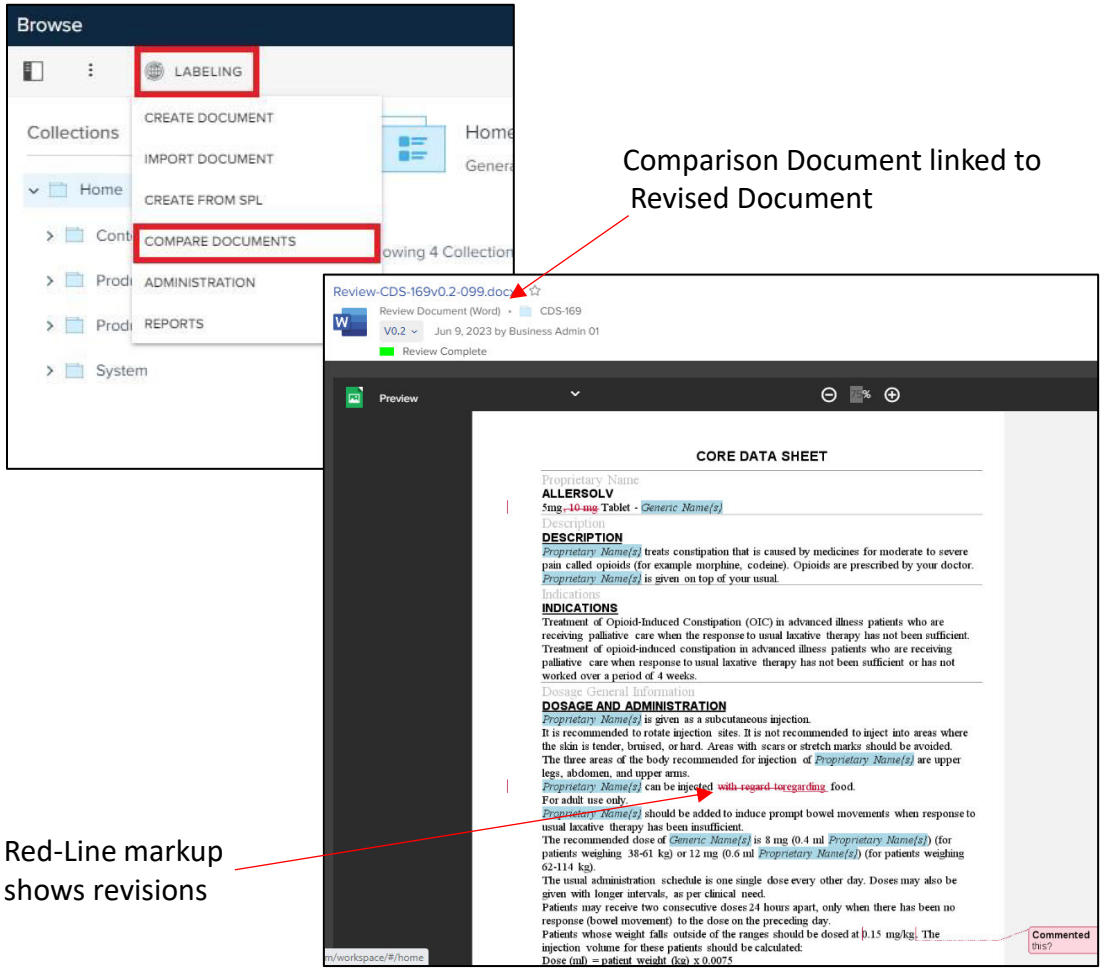
- Home
- Preview
- History
- Properties
- Refresh

*Note: Boxes show the relationship for navigating content and components*

# Compare Documents: Easily highlights the Change Between Two Versions

Evaluates elements within document components and displays the changes in Red-Line markup




*Note: Differences between the selected versions are displayed*





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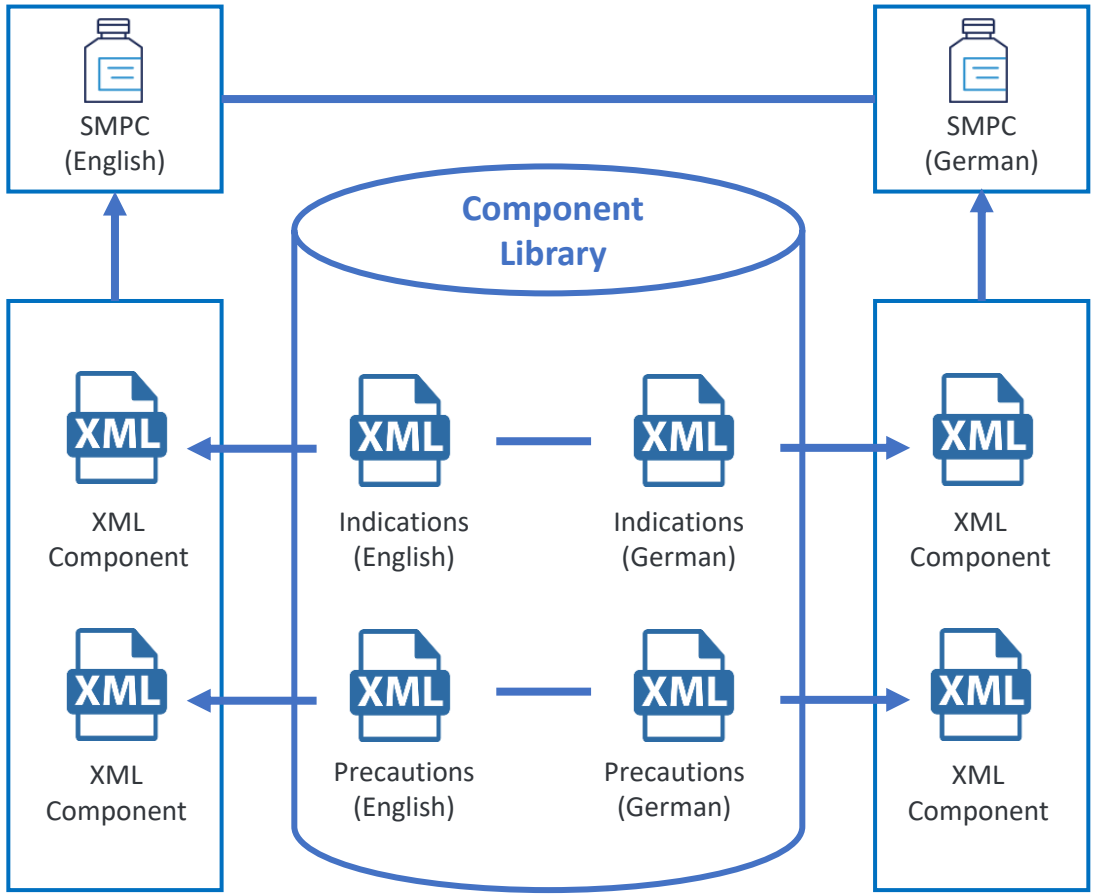
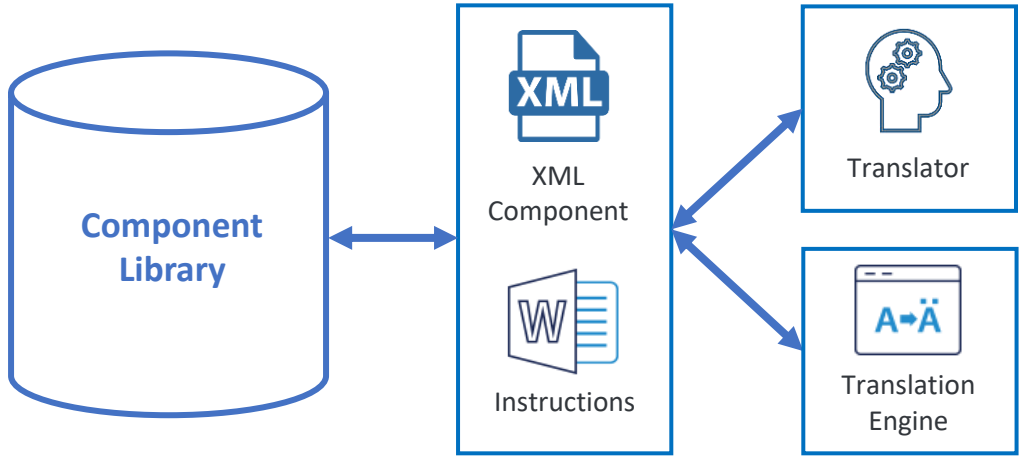
# Translation Management – Human in the Loop

Label components and their translations are available for reuse




Labeling content can be manually or automatically exchanged with translators and translation engines





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