CASE STUDY

IMPLEMENTING A STRUCTURED CONTENT MANAGEMENT SOLUTION FOR PRODUCT LABELING IN A GLOBAL PHARMACEUTICAL COMPANY

BUSINESS CHALLENGES

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. As information is added and changed over time, manual business processes and technologies increase the risk of:

- Errors and inconsistencies being introduced when manual copying-and-pasting of content is performed to maintain consistency from core to regional labeling documents
- Difficulty when trying to locate the most recent, updated version of content
- Manual efforts to compare versions of content across documents to identify changes and make key decisions
- Delays in completing labeling updates due to the labor-intensive and time-consuming process
- Labeling inaccuracies potentially leading to warning letters from regulators or even a product recall

THE ARBORSYS SOLUTION

We developed and delivered a structured content management (SCM) solution to the client by pairing the required business processes with the appropriate technologies. The ArborSys team worked collaboratively with the client to:

- Organize content from the primary labeling documents – Company Core Data Sheet (CCDS), Company Core Safety Information (CCSI), US Product Information (USPI), and Summary of Product Characteristics (SmPC) – into content fragments or "topics"

- Categorize the topics as either reusable or unique based on certain qualifiers (e.g., formulation, region)
- Structure the topics by identifying their associated metadata, business rules, governance, etc.
- Generate an information model of the topics (see graphic below)
- Implement a SCM solution by configuring the information model, including structured and reusable topics, in the client-selected SCM tool, DitaExchange
- Implement extensions to the core SCM platform to support the labeling business processes to manage multiple branches of labeling documents, versions, and easy comparison of changes to topics
- Extend the authoring interface in MS Word to include custom add-ins to support the labeling process

The following diagram is a representation of the information model and configurations:
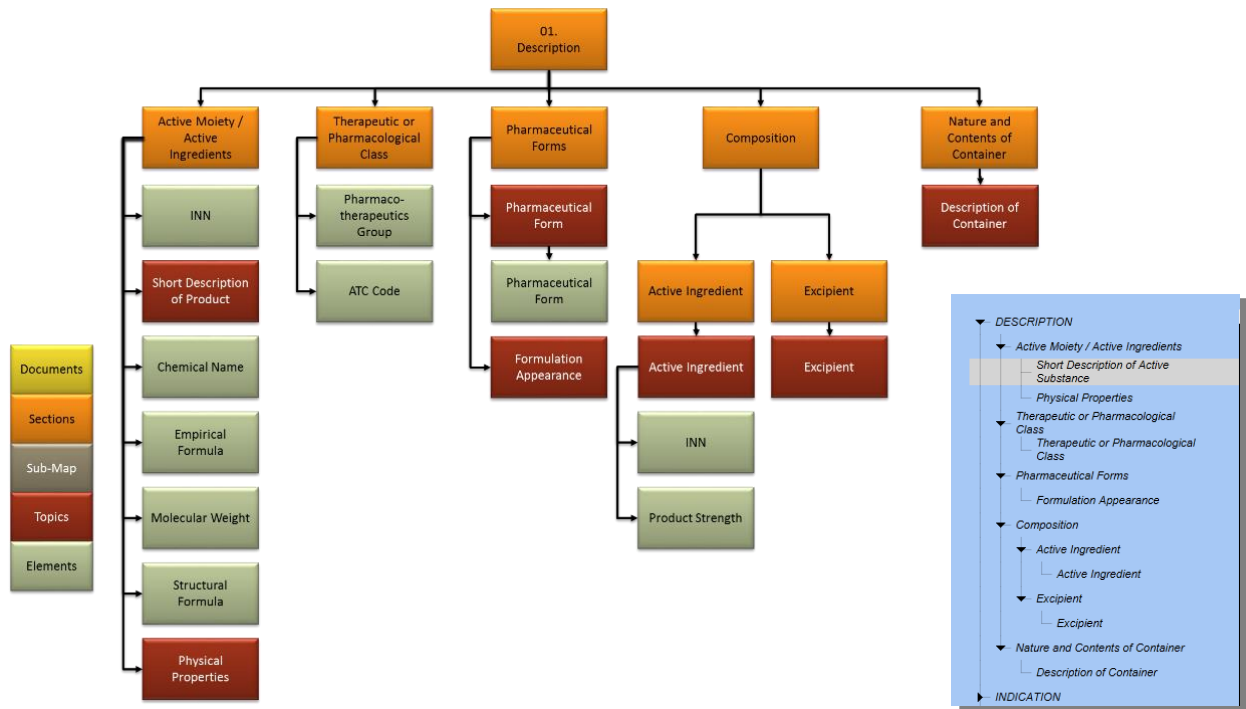
The following screen is representative of the labeling documents and reporting dashboards implemented:
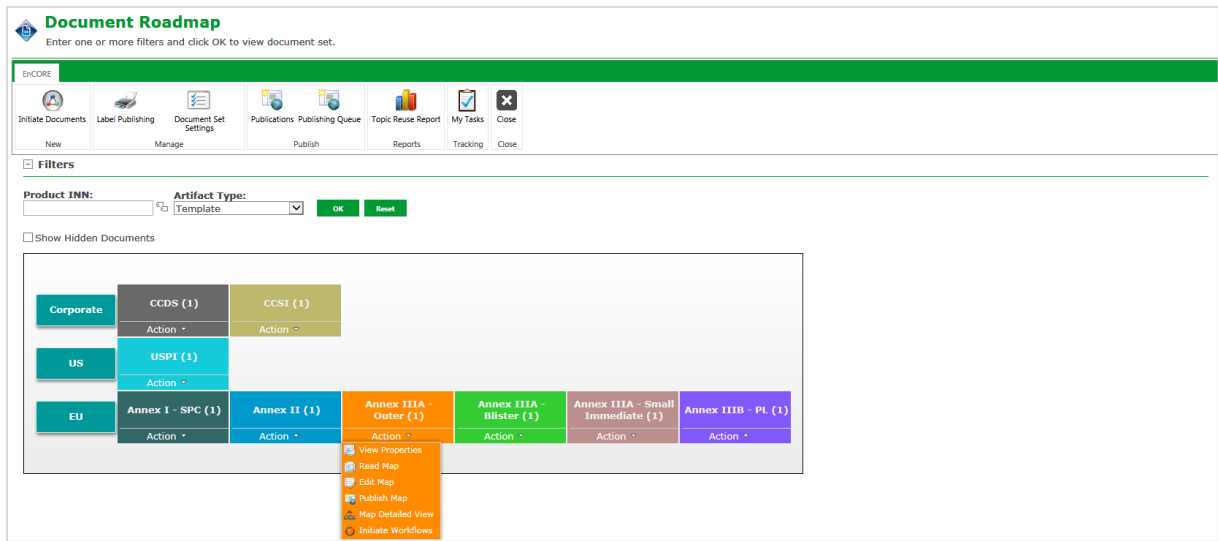
VALUE DELIVERED

The SCM solution allowed the client's organization to more effectively manage all of their labeling information both within and across company boundaries. The solution resulted in significant benefits such as:

- Significant time savings when assembling labeling documents from reusable content (topics) that have already been reviewed and approved by appropriate personnel
- Easy selection and incorporation of specific content based on region
- Targeted review and approval of new content, accelerating document finalization
- Rapid response to a regulator's request for more information or labeling changes
- Changes or updates to the core documents will automatically propagate to all related downstream documents, ensuring accuracy and consistency
- The client was able to conduct a proof-of-concept for the core labeling documents within a short timeframe, and provide useful feedback to enhance the solution for broader needs

For more information on the SCM tool we utilized, follow the link below:

http://ditaexchange.com/project/sanofi/