CASE STUDY

UTILIZING A STRUCTURED CONTENT MANAGEMENT SOLUTION FOR GENERATING CLINICAL DOCUMENTS IN A GLOBAL PHARMACEUTICAL COMPANY

BUSINESS CHALLENGES

Our client, a major pharmaceutical company, was faced with a growing amount of clinical information that needed to be managed more efficiently. As their information grew in complexity and accumulated over time, they found it increasingly difficult to manage it all via manual business processes and technologies. This led to an operating environment challenged by:

- Prolonged writing and review timelines leading to a drain of resources
- An inability to rapidly search for and identify desired information
- The introduction of inconsistencies or errors when the same content was revised in multiple documents
- Difficulty “locking” final, approved content to ensure accuracy

THE ARBORSYS SOLUTION

To meet these challenges, ArborSys provided leadership and domain expertise in helping the client deploy a first-of-its-kind structured content management (SCM) platform that would transverse the company’s research and development efforts. Specifically, the ArborSys team:

- Performed an assessment of the current operational environment (stakeholders, processes, etc.)
- Established a targeted process vision for both the business and technology
- Guided the client to select the “best fit” technologies
- Led in the development of an information (content) model and subsequent implementation
- Provided the support necessary to meet business and technology needs

The ArborSys SCM solution was undertaken in four phases:
• Phase 1, Business Requirements: Identification of the overarching business capabilities and requirements
• Phase 2, Technology Identification and Development: Evaluation of available SCM technologies in market place; tool evaluation and selection; sandbox installation, configuration, integration, and validation
• Phase 3, Release Planning: Adaption of the SCM tool to business needs; creation of the initial information model and configuration/ development in the tool; socialization of the new SCM business model with end-users
• Phase 4 Implementation: Implementation of the new SCM business processes and services, including training, rollout and adoption, and establishment of a governance and support structure

The phased approach facilitated an iterative continuous improvement process that was instrumental in:

• Determining best practices and process impacts
• Determining how to reuse content across documents and deliverables
• Creating an information design to support reuse and quality
• Implementing process efficiencies which was to be gained over time
• Developing an ability for the business to manage information at a component level – minimizing “document centric” views, leveraging the reusability of information, and reducing authoring and review cycles for previously approved content

The continuous improvement approach required a high degree of planning and prioritization. An Agile approach was implemented not only for the program, but also for the development and implementation phases.
After implementation of the first few iterations of the project, the ArborSys team provided continual leadership and guidance during the ongoing iteration of the SCM tool and related processes. ArborSys also assisted the client in transforming the SCM processes and delivery of the authoring and document publishing services as a “Services Model” that could be staffed and delivered using an Operational team.

**Value Delivered**

- The delivered SCM solution allowed the organization to efficiently manage all of their clinical information both within and across company boundaries. The solution has achieved significant tangible and intangible benefits, including:
  - Reduction in document authoring time by focusing on new content and minimizing the cyclical churn of reviewing previously approved content
  - Creation and management of libraries to manage standard text and content that is used for in clinical documentation
  - Easy search and identification of desired content from libraries for inclusion during the authoring process
  - Rapid and consistent propagation of content changes in all related documents
  - Control of approved content with security policies