CASE STUDY

CONTROLLED DOCUMENT MANAGEMENT – IMPROVED COMPLIANCE, REDUCED RISK

BUSINESS CHALLENGES

Our client, a leading provider of oncology and medical imaging read services for global clinical trials, was faced with a number of challenges during a period of rapid expansion. A key business need was the adoption of a configurable framework for implementing GxP-compliant controlled content solution. The system was required for the management of documents related to their clinical and organizational operational procedures, as well as the protocol specific charters and project documents. During its initial years, the organization, as many others, created manually intensive processes to manage its controlled documents. Over time, due to organizational growth and increased volumes, these processes evolved and became more complex and less manageable. In addition, effective controlled documents were made available to consumers through a shared file server resulting in security and compliance concerns.

In order to improve process efficiencies and standardization for the creation, updating, review, approval, and publishing of controlled documents, as well achieve higher levels of compliance, the client sought to implement a Controlled Document Management Solution using state-of-the-art and industry standard technologies.

THE ARBORSYS SOLUTION

Working collaboratively with this client, the ArborSys Group implemented a Controlled Document Management system to support the internal processes for the creation, review, electronic signature, approval and final effective watermarking and publishing of all controlled documents. The Quality Assurance Group, who owned these processes, was instrumental in working with our team to define and establish the standardized life cycles, workflows and electronic signature policies for the system. The published documents were made available to the consumers through an Intranet portal. Controlled documents addressed through this solution included:

- Corporate and Departmental Standard Operating Procedures (SOPs);

- Clinical study-related project charters and amendments governing the clinical processing and read services;
- Protocol specific documents.

Our team was engaged to work with the client to:

- Define the business, functional, and technology requirements;
- Establish a comprehensive design;
- Configure and develop the application;
- Perform integration testing;
- Support client validation and implementation.

EMC's Documentum Compliance Manager (DCM) 5.2 SP1 provided the facility for managing the effective controlled documents, including:

- Management of the underlying workflows and lifecycles;
- Electronic signatures;
- Audit trails;
- Watermarking;
- Publishing of the approved documents to the client intranet portal.

In order to provide enhanced usability for end-consumers, the ArborSys team published the approved documents to an intranet portal, providing consumers with simple interfaces to easily drill-down through a standardized taxonomy, and securely locate/view documents at either the corporate or departmental level.

ArborSys also worked with this client to migrate the application to DCM 5.3 to enhance the solution and address the limitations inherent in the DCM 5.2 version.

VALUE DELIVERED

Using our significant domain experience and technical expertise, our team was able to successfully partner with our client to deliver a solution that significantly improved process efficiencies for the management of controlled documents within the organization, and delivered substantial business value to the client, including:

- Standardized processes for document creation, updates, and management;
- Improved security and audit of controlled document processes;
- Standardized process for electronic signatures;
- Higher levels of FDA CFR Part 11 compliance;
- Reduced operational risk.