



## GOLD LION ASSOCIATES, INC.

PROJECT MANAGEMENT & BUSINESS ANALYSIS  
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### INDUSTRY

Pharmaceuticals

### ROLE

Senior Project Manager and  
Business Analyst

### CHALLENGES

The process for producing a New Drug Application (NDA) and International Marketing Application (IMA) was predominantly manual.

### SOLUTION

Gold Lion Associates worked with the client to architect and implement a system to reduce the cycle time required to create and publish new or supplemental filings to the FDA and ensure consistent content and format.

### BENEFITS

The new system eliminates the cumbersome creation, review and assembly of Microsoft Word documents and associated PDFs for FDA submissions. It decreased the cycle time needed to create new or supplemental filings and to ensure consistent content and format across filings.

**The Chemistry, Manufacturing, and Control (CMC) organization of a major pharmaceutical company, responsible for accumulating and assembling information for the CMC sections of NDA and IMA submissions, needed to reduce the cycle time required to create and publish filings to FDA and ensure consistent content and format.**

**Challenges** – The Chemistry, Manufacturing, and Control (CMC) organization of a major pharmaceutical company is responsible for producing the CMC sections for FDA submissions. The process for producing a New Drug Application (NDA) and International Marketing Application (IMA) was predominantly manual. The major problems are as follows:

1. The process of filing an NDA or IMA was manual and very cumbersome.
2. The directory structure for storing the documents was not standardized.
3. Preparing the documents is an iterative process and hinders concurrent document development.
4. NDA and IMA documents were not linked. Since they are separate documents, any future changes to the NDA must be manually reflected in the IMA.

The Company decided to create a system that provided a reproducible and effective process for successfully creating and publishing FDA related documents.

**Solution** – Gold Lion Associates worked with the client to architect and implement a system to reduce the cycle time required to create and publish new or supplemental filings to FDA and ensure consistent content and format.

Contributors/authors can now access the system functionality through a Visual Basic Graphical User Interface (GUI). By double clicking a template icon in a tree structure, or selecting a menu item, the user accesses a Microsoft Word template stored on a secure network drive. The template takes the user through a series of steps, providing the necessary information to complete the Microsoft Word document. Once the document is completed, the Microsoft Word document is saved in the Panagon DMS repository. The next time the user accesses the system, the Microsoft Word document appears as a node on the tree structure in GUI.

To review a Microsoft Word document, the author accesses the system and double clicks the node on the tree view that represents the current version of the Microsoft Word document to be reviewed. The document is presented to the author in “Read Only” mode unless it is formally “Checked Out” of FileNet’s Panagon Document Management System (DMS). If changes are required, the author must, “Check Out” the Microsoft Word document from the Panagon (DMS) in “Write” mode.

The outputs of the authoring process are the Microsoft Word document and associated PDF file which are stored on a secure network drive. Authors then physically store the Microsoft Word document into the DMS. As a consequence of this action, the associated PDF file is also stored in DMS.

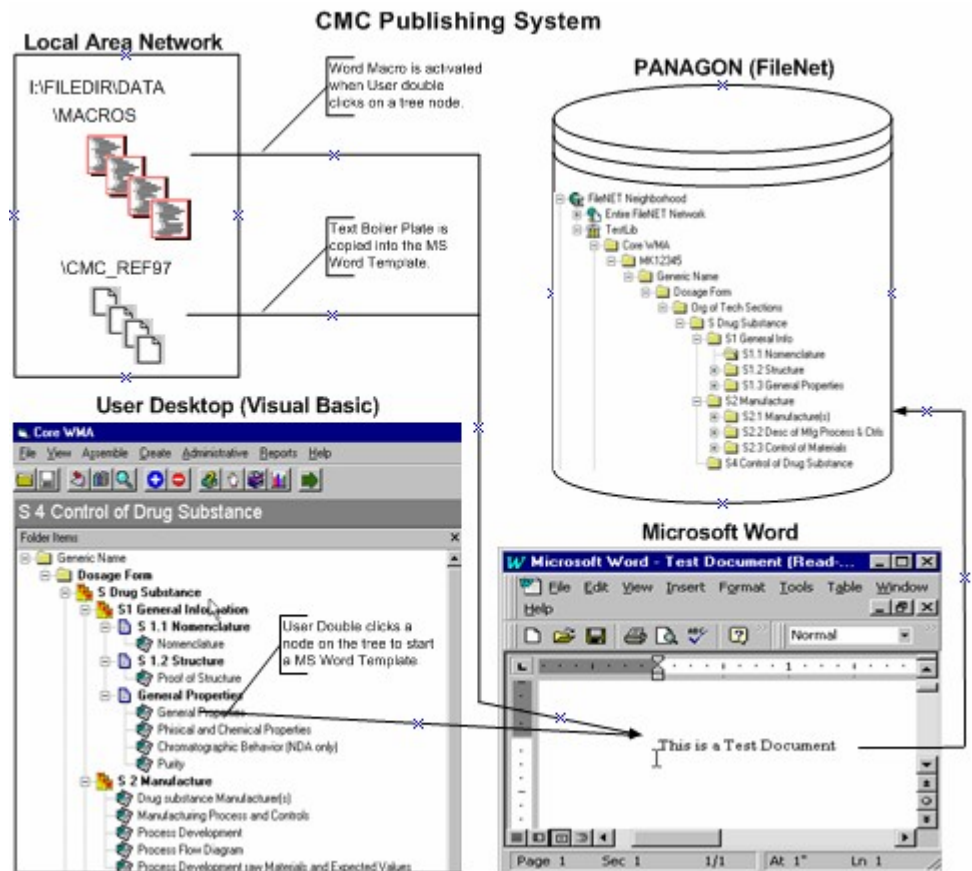
To keep track of the position of each Microsoft Word document and associated PDF file in the hierarchy of documents that comprise a CMC submission, a structure is maintained in the Oracle database by submission type that keep track of the parent-child relationship for each document.

## PROJECT SYNOPSIS

The system generates information to be sent to FDA as part of an NDA or IMA and, therefore, it must comply with “21 CFR Part 11” and FDA’s Guidance for Industry Documents, while increasing process efficiencies. A complete set of system documentation, including: System Requirements Specification, System Detail Design, System Technical Design, templates, user manuals, and training materials.

Extensive system testing was planned, executed and documented because this was an FDA validated project. Test cases were written from user and system requirements documented in the System Requirements Specification. A Traceability Matrix was maintained to insure that the functionality described in the System Detailed Design and System Technical Design matched the functionality described in the System Requirements Specification.

Merging these components assembles an FDA submission. Each type of submission, such as NDAs and IMAs are assembled from a different subset of these components in the order required by that type of submission. Only the latest files that are checked into the DMS are available to be assembled into a CMC submission.



**Business Benefits** – The new system eliminates the cumbersome creation, review and assembly of Microsoft Word documents and associated PDFs for FDA submissions. It decreased the cycle time needed to create new or supplemental filings and ensured consistent content and format across filings. The system will facilitate the reduction in cycle time by making use of Microsoft Word templates that use “Boiler Plate” text and “Macros” to streamline the preparation and review process of CMC submissions. This will facilitate the concurrent creation of filings for multiple markets.

Authors and reviewers can now download and collaborate on documents stored in FileNet’s Panagon DMS. Document integrity is maintained by forcing authors and reviewers to use the check in/out facility of the document management system. The client was able to deploy standardized processes and achieve considerable cost savings and reduced the amount of time significantly for assembling and publishing FDA submission documents.