VALIDATION ASSOCIATES
Electronic Document Management System

Case Study
Challenge

The client faced huge challenge in implementing a successful unified Document Management System. Earlier the client had an unsuccessful experience in implementing the solution. Our biggest challenge was to make the client understand our approach and how it differs and how will it contribute to their success.

Implementing a unified Document Management System is not easy as it optimizes the storage, retrieval, distribution and security of the documents throughout the organization.

Following components were evaluated for risk and implementation:

- Integration
- Metadata
- Indexing
- Capture
- Storage and Retrieval
- Workflow
- Security
- Collaboration
- Versioning

Approach

Our implementation began with a series of workshops to obtain better understanding of the client’s environment and business requirements. Based on the information and the business requirements discussed, a team from Validation Associates LLC created a tailor implementation of the Electronic Document Management System to the client’s needs.

Our approach consisted of the following:

- Analyzing the business requirements with the client’s business team.
- Developing the Validation Plan.
- Performing the Risk Assessment for the computerized system concerning regulatory, legal and information security topics.
- Developing the functional requirements documents.
- Developing and execution of the Installation Qualification, Operational Qualification and Performance Qualification test scripts.
- Developing and maintaining the Deviation Reports.
- Developing Traceability Matrix to track the user requirements to the functional requirements, design specification and the IQ/OQ/PQ test script references.
- Developing the Validation Summary Report to provide a summary of the validation activities and executed deliverables.
- Training of the end users on the system.

Client

The client is a leading research oriented pharmaceutical company engaged in development, manufacture and marketing of pharmaceutical products.
Benefits

Upon the successful implementation of **Electronic Document Management System**, the client achieved the following benefits:

- Streamline document control (Create, Edit, View, Import/Export, Versionize, Delete, Find and Changing Attributes and Permissions).
- Accessibility of the documents for review, updates and approvals.
- Generation of Reports and Audit Trail.

Technologies

The following technologies were used during the implementation of the **Electronic Document Management System**

- Citrix Server
- Central Designer
- Inform
- Livelink
- Atlas
- Kofax
- Crystal Reports
- Microsoft .Net Framework
- MS Sequel Server 2000