

GLOBAL BIOTECH COMPANY UTILIZES ELECTRONIC DOCUMENT MANAGEMENT SYSTEM TO INCREASE PRODUCTIVITY



The Customer

This customer is a global biotechnological company specializing in discovering, developing, and delivering therapies for the treatment of different diseases to patients worldwide.

Business Drivers

Development of drugs involves different processes with multiple steps in each process. Each step has large amounts of data that need to be maintained securely with detailed audit trail of each entry and modification. Same processes are carried out for manufacturing drugs in various batches and information about each batch process and steps need to be clearly maintained.

This customer used to maintain this information in spreadsheets which were uncontrolled. Each batch required replicas to be created which made whole process difficult to manage and control. They were looking for a 21 CFR Part 11 compliant solution to replace the current procedures.

Solution

The customer implemented CIMINFO's proven 21 CFR Part 11 Compliant eInfotree™ - Electronic Document Management System (EDMS) which allows organizations to manage digital content, including scanned paper documents, faxes, prints, application files, electronic forms, web content, multi-media files and emails. eInfotree™ also authorizes organizations to automate business

processes, reduce the time and cost of performing important business functions, improve organizational efficiency and address the need for regulatory compliance through the management, control and sharing of digital content with employees, business partners, customers and other constituencies.

eInfotree EDMS provides the following features:

- Pure web-based solution which can be accessed from anywhere using a web browser
- Configuration of study and batch folders and files in a systematic way with access privileges to all authorized users
- An option to quickly migrate spreadsheets into web based forms with same look and structure as needed
- Spreadsheet data now available in database leading to vast reporting options
- Full 21 CFR Part 11 compliant solution for spreadsheets with each entry and change of data cell recorded in audit trail
- Maintaining associated documents with batch documents in a centralized repository.
- Advanced functionalities for their spreadsheets such as e-signatures and cell level security.

- Spreadsheet compare tool to quickly see the changes between different batch processes.
- Batch master templates to be maintained at centralized location for easy reference in new batch processes
- An option to export data to external third party systems.
- Automatic email notification to all related users for specific actions in the system
- An audit trail of each action performed on the file, including viewing of documents
- Extensive search functionality based on different criteria including the contents and meta data
- A workflow application which automates the file approval process that can be tracked and analyzed for process optimization
- Quick identification and retrieval of documents including spreadsheets and no more lost or misplaced documents
- No more confusion as to which batch process template is the latest one to start a new batch
- Ability to use batch data for effective reporting and for exporting to third party systems
- Manage retrieval and archival efficiently
- Notifications and comparison features reducing the time of review and approval
- Business processes are optimized based on the actual data to get the maximum productivity from the team members

Business Benefits

The benefits after implementation of the system included:

- eInfotree's patent-pending ECM architecture allowed the Client to mimic its business processes using a secured 21 CFR Part 11 Compliant repository. A regulated, controlled and compliant Digital Nervous System with unified access throughout the workgroup, department and enterprise was brought in after the implementation.
- No more multiple copies of spreadsheets at different file shares

Value

By selecting CIMINFO, the customer received tremendous value:

Business: Well defined hierarchical storage of documents, quick retrieval and electronic Workflows totally mimicking their business processes reduced the overall time taken in completion of a Batch Process. Detail of every change in spreadsheet and form data is traceable.

Productivity: CIMINFO re-engineered and automated the company's business processes with notifications to concerned individuals about the changes and jobs waiting for them. The review process became faster with the availability of collaboration tools and comparison features. Since ad hoc workflow tracking was possible, the company could easily optimize its business process for better productivity.

About CIMINFO

CIMINFO Software, Inc. provides a wide range of software solutions and compliance services that reduce costs and improve operational efficiency while complying with 21 CFR Part 11 and GxPs. CIMINFO anticipates, defines, evaluates and solves the technical and regulatory issues that arise in a constantly changing environment to help clients achieve their business goals. The firm brings to bear 25 years of innovation, experience and knowledge in designing, developing and implementing technology solutions from the plant floor to the top floor.

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