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Software tools for efficient
Notes® development and
simple, secure administrator
control

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Case Study: Pharmaceutical - FDA Compliance

Teamstudio® CIAO!® Client

A Major International Pharma Group Located in Europe

Client Overview

As a leading pharmaceutical company in Europe; traded on Euronext Paris, this worldwide specialty Pharma group has sales in excess of €850 million. The client employs more than 4,000 people worldwide in support of their customers located in more than 100 countries.

The Challenge

The company has more than 30 business critical Lotus Notes® applications in use throughout the company, with more than 1,200 users accessing the applications. The entire Notes infrastructure is supported by 2 Notes specialists. Many of their applications are directly related to their core business including authorizations for clinical tools, factory accident control and recruitment.

The company's international development is a priority for the future, and the United States is a key market for the company. In order to continue marketing products there, the company must meet the requirements and receive approval from the Food and Drug Administration (FDA) which monitors human and veterinary drugs, biological products and medical devices and more, to ensure they are safe and effective.

FDA audits require the ability to generate an audit history for quality control documentation. The client was challenged to meet this regulatory requirement because it lacked a Change Management and Control System for their Lotus Notes development environment.

Failing an FDA audit would result in losing the US market to a competitor. This might also damage the company's reputation in other markets served. As a result, passing the FDA audit was critical to the continued success of the company.

The Teamstudio Solution

Teamstudio acquainted the company with CIAO! Client, a software tool that allows Notes developers and administrators to work on the design of the same database at the same time, without generating save conflicts on the design elements on which they are working. CIAO! also allows previous versions of design elements to be stored, which can be restored if required. Each time a new version of a design element is checked in, the developer enters information about the changes that were made. Teamstudio CIAO! maintains a log of all the changes to each design element, allowing rollback to any previously stored version of that design element.

When viewing the history of changes that have been made to a design element (such as a form, view or subform), CIAO! allows the developer to compare the two versions of the element, displaying exactly what has changed from one version to the next.

When the design of any database is ready for release, a version can be made. When a new version is created, all of the design elements are check pointed with the same date and comment, and a complete copy of the database design is stored in the log database. This provides complete configuration control of the Notes and Domino® development activities.



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the right to change product specifications
without notice.



Case Study: Pharmaceutical - FDA Compliance

Teamstudio® CIAO! Client

One of the Largest Beverage Producers in Europe

The Result

Compliance achieved! Teamstudio CIAO! is implemented and all FDA affected applications have been put under CIAO! control for version management. The CIAO! log was provided to the FDA for the required quality control documentation, as this provided the full history audit.

Over time, all of their applications have been placed under CIAO! control because of the efficiencies gained. Prior to their use of CIAO!, a great deal of time was spent on manual tasks. Then, an entire day could be spent rolling back to a previous version of a design element. Today with CIAO!, it takes 30 seconds, so the saved time can be used on more important tasks. And thanks to CIAO!, producing audit trails is now automatic and painless.

The client has not calculated the actual cost savings since the introduction of CIAO!, but it is easy to see from the example above that the savings are significant in terms of time and money. The client did say "It is difficult to measure the cost of failing to meet the FDA's compliance requirements. But it has to be tremendous!"