



Enhancing Webtop 5.3 for Pharmaceutical Compliance



Controlled Documentation

overview

Technology Services Group teamed with a major pharmaceutical firm to design and implement a streamlined change management process leveraging best of breed software products. The system provides users with an efficient way to create, route and approve documents and change requests without compromising product safety, regulatory compliance and manufacturing consistency.

solution

By implementing the following features, TSG designed a configurable system that provides an automated approach to efficiently manage and process documents and change requests.

- **Dynamic Change Request** – The change request is built dynamically according to how a user answers a series of questions regarding the change. Each answer influences which additional questions are presented to the user ensuring a user is only asked to provide relevant information.
- **Dynamic Approval Assignment** – How a user completes a change request provides the system with the correct information in order to determine the required approvers for the change request. This allows for the knowledge of the approvers to be built into the system.
- **Multi-Document Approval** – A user is able to route one or more documents with a change request for approval and apply one electronic signature to the entire packet. This feature significantly decreases the document approval time.
- **Dynamic Headers and Footers** – The system dynamically applies a header and footer to each document that contains variable information (e.g., Document Status, Effective Date). This guarantees data displayed on a document is accurate and reflective of the document status at view and print time.
- **Consumer-Only Interface** – Users who only consume and view documents are able to access a simplified viewing interface. This interface reduces user training as well as the volume of users required to access the authoring/approval interface.

result

The configurable architecture allows the system to quickly react to business changes without requiring re-validation efforts associated with coding changes. Additionally, the change request automation decreases the process time and costs associated with the generation of a change request. The end result is shorter manufacturing cycles and reduced costs while providing assurance of quality in the management of the change process for controlled documents.

contact information

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solution overview

industry

Pharmaceutical

challenge

To improve the efficiency of document change control processes and reduce the risk of non-compliance.

solution

A web-based application that automates the management and processing of documents and change requests.

result

Streamlined change management processes that decreases the manufacturing cycle times while ensuring regulatory compliance and maintaining product quality.