Leading global healthcare company determines its manual processes pose high risk for non-compliant clinical labeling content

Implementation of Glemser's ComplianceAuthor™ system provides automated, validated alternative that ensures accuracy and compliance

Following an analysis of deviations within its Label Definition Contract and Regulatory Rules, a leading global healthcare company—provider of pharmaceuticals, vaccines, and consumer healthcare—determined its in-house application for clinical labeling to be a high compliance risk. Its onerous, manual process was prone to human error and misinterpretation leading to incorrect or incomplete label information.

Challenge

Industry-wide, regulatory authorities have demonstrated increased focus on data integrity. Beyond the need to meet and exceed regulatory standards, non-compliant labeling will likely invalidate a study, could lead to product recalls costing millions, or adversely affect the patient. Study delays may give competitors the ability to be "first to file" along with the advantages that affords. Non-compliance can also significantly damage a company's credibility and reputation.

Beyond the elements of a label—protocol number, batch number, drug name and strength, directions for use, storage conditions, and caution statements—each label must also correspond to type of study (i.e. single blind, double blind), package type (i.e. bottle, vial), and where the trial takes place. All of these variables require different elements to be present on a label, potentially translated into different languages. All elements must also meet Health Authority and local country-based requirements. It is this variability that makes the manual application of clinical labeling rules so complex and vulnerable to non-compliance.

In this case, Good Manufacturing Practice (GMP) deviations were attributed to the burden of manually maintaining the record, reliance on manual change notifications, and lacking information verification. Seeking an automated and validated alternative to its manual, paper-based system, the company engaged Glemser to implement a clinical labeling solution that would not only minimize risk and exceed regulatory expectations, but also to enable it to confidently demonstrate control during audits.

Solution

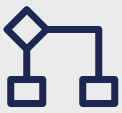
Glemser's ComplianceAuthor™ for Clinical Labeling manages regulated content through all stages of the document's lifecycle to reduces the potential for human error as well as label creation time. ComplianceAuthor™ for Clinical Labeling is built on Documentum's architecture to provide enhanced functionality required to enable authorized users to manage content in XML format. It consists of two components: an authoring component and a Document Management System (DMS) component.

The authoring component enables the user to easily author phrases and study data. The system utilizes a library of approved phrases and a business rules engine to predefine a set of phrases required for a label based on information such as country, label type and package type, as well as a set of predefined questions. The label is initially created in English then, once approved, generated into all required languages based on the phrase translations stored within the system.

The DMS component manages content translations, relationships, version control, lifecycles, review and approval workflows, system notifications, tracking and reporting, audit trail, and security. Authorized users can manage the phrase library and business rules as needed to accommodate changing regulatory requirements and business processes. Change control is built into ComplianceAuthor™ for Clinical Labeling will ensure that processes are followed before making any changes to approved content.

Benefits

ComplianceAuthor™ for Clinical Labeling is a validated system, thus ensuring accuracy and compliance. Its automated components remove paper and enforce business rules through workflow helping the client to compliantly manage rules, phrases, translations and label content. ComplianceAuthor™ for Clinical Labeling then stores and manages client data in a way that is easy to access and report. This significantly enhances operational compliance and data integrity in client supply chain facilities. Data is reliable, complete, consistent, accurate, and secure throughout the data lifecycle.



Easy-to-follow workflows define study information

Direct link to phrases and translations with automated translation service

Business rules engine to remove manual interpretation and risk of error

Attribution achieve via real-time e-signature required for each approval workflow

Electronic record with back-up system rather than paper-based

Real-time data system for complete data

Rapid access to data for traceability

Enforced change controls for compliance

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