Clinical Labeling Development Solution

The Challenge

When conducting clinical trials, pharmaceutical companies must provide investigators and patients with information about the medicines being administered. This information is called “product labeling”. Since clinical trials are conducted worldwide, product labeling documents must be translated into multiple languages and meet applicable country-specific regulatory requirements. Product labeling documents are typically authored as language-specific “panels” and published into “booklets” containing all study-specific languages.

Companies spend an exorbitant amount of time authoring product labeling documents, translating content into multiple languages and ensuring compliance with local regulatory requirements. Since bringing new products to market faster is extremely important, pharmaceutical companies need to implement software solutions to gain efficiencies in the authoring, review, approval and translation of labeling documents used in clinical trials.

The Solution

Glemser’s Documentum-based CLD solution improves the speed in which clinical labeling documents are created, managed and published. Built-in translation memory enables language translations to be generated quickly and accurately. The translation memory can be managed by authorized users and will grow automatically over time as users translate new English content.

Since clinical trials are often conducted in multiple countries, our CLD solution will ensure that all labeling documents comply with country-specific regulatory requirements. Using a configuration wizard, authorized users can define and manage country-specific business rules, and the system will ensure compliance with these rules. Skilled Glemser consultants can help you with any part of your clinical labeling implementation project. By leveraging best-practice configurations and implementation accelerators, we can rapidly implement, validate and deploy a production solution to meet your company’s timeline.

Solution Benefits

Ensure compliance with country-specific regulatory requirements regarding the content of clinical labeling documents.

Improve efficiency by reducing the time required to create, review, approve and publish clinical labeling documents.

Reduce costs by leveraging built-in translation memory to reduce the time and effort needed to translate clinical labeling documents into multiple languages.

Increase productivity by replacing manual procedures with automated workflows and electronic approvals.

Reduce risk by ensuring the correct, approved version of clinical labeling content is always used.

Reduce administration by allowing authorized users to manage clinical labeling business rules and translation memory using a user-friendly graphical user interface.

Improve collaboration by leveraging out-of-the-box Documentum workflow functionality.

Contact us today or visit us online.
(610) 317-9400
inquiry@glemser.com
www.glemser.com

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