Glemser TECHNOLOGIES

< xmLabeling® />

A Comprehensive Solution for Managing Global Pharmaceutical Labeling Content

xmLabeling® 5.0 enables companies to streamline global labeling business processes and meet the regulatory requirements for submitting XML-based labeling content

The Labeling Challenge: Complex Processes and Evolving Submission Formats

Pharmaceutical companies spend a great deal of time managing product labeling documentation such as package inserts (PIs), summaries of product characteristics (SmPCs), and core data sheets (CDSs). The same information is often duplicated in multiple documents for various product strengths, dosage forms and presentations, resulting in a vast set of labeling documents that are difficult to manage and keep synchronized.

Meanwhile, the Federal Drug Administration (FDA) and the European Medicines Agency (EMEA) are implementing rules (SPL and PIM) regarding the electronic submission of labeling content in XML format.

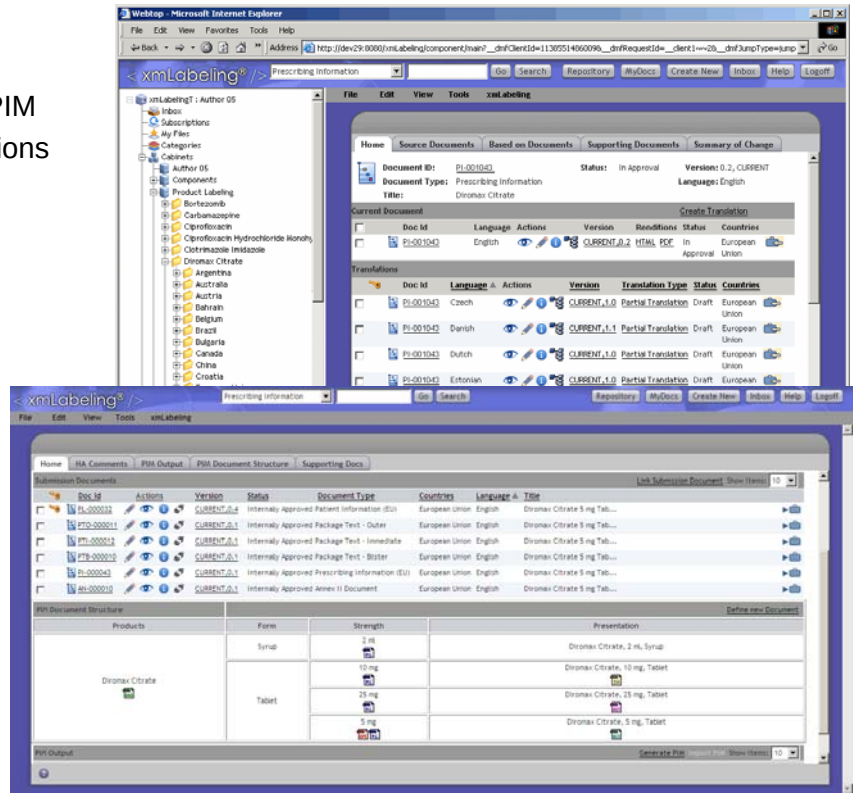
As a result, life sciences companies have a double challenge. In the short term, they need to put in place systems and processes to ensure compliance with the new regulatory requirements. In the long term, they need to make strategic decisions to address the fundamental requirements of managing their global labeling content in a manner that reduces cost and complexity.

xmLabeling® 5.0 is an Out-of-the-Box, Comprehensive Labeling Solution for Life Sciences Companies

- **Documentum-based**: xmLabeling is built on Documentum 5.3, using the Webtop interface. Designed to be 100% compatible with Documentum's architecture, xmLabeling is an accredited Designed for Documentum application that will coexist effectively with your Documentum environment.
- **Enables Re-use of Labeling Content**: xmLabeling enables the creation, editing, approval and management of product labeling content as re-usable, agency-neutral XML components. Content common to multiple documents can be easily linked or re-used, reducing costs and ensuring the use of the correct, approved content.
- **Generates SPL and PIM**: xmLabeling allows the generation of the SPL and PIM formats required by the health authorities directly from your labeling content. By using an agency-neutral format for labeling content, xmLabeling removes the need to manage multiple versions of the same content.
- **Completely Configurable**: xmLabeling is a completely configurable, out-of-the-box solution, eliminating the cost, complexity and risk associated with custom applications.

xmLabeling 5.0 Solution Benefits

Glemser's xmLabeling solution enables regulated companies to:



- **Ensure compliance** with SPL and PIM by generating agency-specific renditions for electronic submission
- **Improve efficiency** by reducing the time required to create, review, approve, and manage product labeling documents
- **Reduce costs** by re-using documentation components in multiple labeling documents and allowing changes to be made once and applied in all places
- **Increase productivity** by replacing manual procedures with automated workflows and electronic approvals
- **Reduce risk** by ensuring the correct, approved version of labeling content is always the one used
- **Reduce complexity** by allowing the organization to manage a single set of labeling content while still meeting output requirements in multiple renditions such as XML, HTML, PDF, and MS Word

xmLabeling 5.0 Architecture

- xmLabeling is a Documentum 5.3 WDK application, designed to maximize compatibility with other Webtop applications.
- xmLabeling has received accreditation as a Designed for EMC application, EMC Documentum's program for ensuring architecture compatibility.
- For XML editing, xmLabeling can work with PTC's Arbortext Editor, In.vision's Xpress Author, or other XML editors

About Glemser

Founded in 1987, Glemser designs and implements XML and content management solutions for life sciences companies. Glemser's solutions help our pharmaceutical, consumer healthcare, medical device, and biotechnology clients effectively address the information management needs of their research and development, regulatory affairs, manufacturing, quality assurance and sales and marketing organizations.

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