

## A Targeted System for Managing Labeling Content and Generating SPL

In reaction to the requirement by the FDA to submit product labeling documents in the Structured Product Labeling (SPL) format, many companies put in place “interim” solutions such as employing file conversion services or directly editing XML documents. For these organizations, xmLabeling for SPL provides a next logical step that incorporates a complete set of document management capabilities as well as the ability to generate SPL.

### *A Complete Labeling Solution – in Twelve Weeks*

With xmLabeling for SPL and the Rapid Deployment program, a complete labeling solution with the ability to render SPL can be in place in your organization in twelve weeks.

The system will allow an easy transition from your current approach to SPL, and your existing SPL documents can be pre-populated into the system. You will have a complete solution that includes a comprehensive set of document management features in place, and a flexible, upgradeable system that you can build your labeling processes on.

xmLabeling for SPL<sup>®</sup> is a complete, out-of-the-box, ready-to-use labeling system. It is pre-configured to allow users to create and edit labeling documents and generate SPL submissions. The documents created are stored and managed in a fully-compliant document management environment, built on Documentum. Specific features include:

- Ability to create, edit and manage labeling documents
- Support for full set of Labeling document types
- Generation of SPL
- Support for a full set of standard renditions (Word, PDF, etc...)
- Importing of existing SPL documents

### *.....Add Implementation Services for a Comprehensive Solution*

Glemser has put together a complete set of services for xmLabeling for SPL that address the requirements of a full system lifecycle implementation. Specific services included in our Rapid Deployment Program include:

- Requirements & Analysis: A set of workshops to collect the requirements for the configuration of the system and introduce the application to the users.
- System Installation and Configuration
- System Testing
- Administrator Training
- User Training
- Validation Services (optional)
- Data Migration (optional)

## 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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