

Glemser has a complete suite of labeling solutions, from conversion services to global content management systems...and each of them supports the SPL Release 4 standard.

Release 4 Dramatically Expands the Scope of SPL

The FDA has announced that in June 2009, a new version of the Structure Product Labeling (SPL) standard will go into effect. This is a major update to the SPL standard that dramatically expands the impact of SPL.

With Release 4, SPL is now required for labeling submissions by new categories of life sciences companies (medical devices and over-the-counter, for example) and dramatically expands the content that needs to be included in every SPL submission.

Glemser has a Full Suite of SPL Solutions

Glemser provides a wide range of labeling products and services that support SPL, from conversion services to global enterprise labeling content management. Each of these solutions supports SPL Release 4:

SPL On Demand™ provides file conversion services for SPL and PLR

xmLabeling® is Glemser's global labeling system for managing XML-based labeling content and addressing both the IM and SPL requirements

xmLabeling® for SPL is a complete, out-of-the-box, ready-to-use labeling system focused on US labeling requirements

SPL for DCM provides a complete labeling solution within the Documentum DCM application environment

Participate in the SPL Release 4 Pilot Program

Glemser is offering a service in the first quarter of 2009 for clients who wish to participate in the FDA's SPL Release 4 Pilot. Participants are provided direct support through the end-to-end process of completing their first SPL Release 4 submission to the FDA during the formal pilot period.

Glemser is the Global Labeling Leader

Since first building a global labeling solution in 2002, Glemser has been the leading expert in pharmaceutical labeling. With four different solutions, Glemser can meet the needs of any company required to submit SPL, whether through conversion services of a global labeling content management system.

More than just a file conversion service, SPL on Demand delivers complete conversion services on a highly tailored basis, with our team directly involved in every step of the conversion and submission process. Our software solutions go beyond simple preparation of submission and include complete document management solutions for package inserts, core data sheets and related documents.

Our experts have been working directly with the FDA and EMEA to ensure successful submissions by our clients for several years. We have the relationships and the know-how to ensure that your SPL Release 4 submission is accurate and speeds through the submission process.

SPL Release 4 Pilot Program

Glemser is offering a service in the first quarter of 2009 for clients who wish to participate in the FDA's SPL Release 4 Pilot. The package of services will include:

- Provide metadata spreadsheet and work with client to gather the correct information from various client sources (manufacturing sites, internal de-centralized divisions)
- Provide access requirements to ESG Portal
- Walk through SPL Release 4 mandate and Agency submission process with client
- Provide SME knowledge of SPL Release 4 mandate
- Provide secure portal (SPL On Demand™) for transfer of metadata, word/PDF/Quark renditions for conversions, SPL files and QC checklists for client



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.

Pennsylvania Office:
60 West Broad Street
Suite 300
Bethlehem, PA 18018
Telephone: +1 610.317.9400

Contact us at sales@glemser.com