Structured Product Labeling (SPL) On Demand

Conversion — Compliance — Quality

Glemser provides a suite of products for customers to manage SPL content in-house, giving users the ability to address US-only or global labeling requirements. In addition, Glemser offers "SPL on Demand" as an outsourced service to generate labeling content in SPL format. Users continue to create, manage and approve labeling content just as they do today. When labeling content is approved internally, users simply transfer labeling files through their preferred method. Skilled Glemser professionals then convert the MS Word documents into SPL format.

SPL on Demand helps bridge the gap between your current capabilities and evolving SPL requirements—delivering high-quality SPL files when you need them. Our SPL on Demand includes access to an SPL expert, a qualified content management system and standard operating procedures. All through a secure internet portal. Our solution also includes validity and quality assurance checklists to help you review and approve your SPL file before submission to the FDA.

Our qualified process is simple

- Sponsors collect labeling content in MS Word, complete a simple spreadsheet and transfer the labeling information through their preferred methods.
- Glemser experts create the SPL files and transfer them according to the Sponsor's preferred method.
- Sponsor retrieves and reviews the SPL file and submits it to the FDA
- FDA reviews the SPL files and provides feedback

Ensure compliance with SPL requirements

Work with professionals who collaborate with the FDA to get submissions right and are experts in structured content authoring and management

Improve efficiency by using a secure Internet portal to transfer files

Maintain document quality through the use of a backend content management system with security, lifecycle management and version control

Manage your SPL files in a submission package that leverages a qualified content management system, operating procedures, and validity and quality assurance checklists

Structured Product Labeling (SPL)
On Demand

Applicant (sponsor)

1 Create/Edit:
- US Package Insert
- NDC Labeler Code Request
- Establishment Registration
- GDUFA Self-ID
- Lot Distribution Reports
- ACA6004 Submissions*

5 Receive SPL R4 Files

6 Perform Quality Review

7 Submit to FDA for Approval

B Receive FDA Feedback

`.doc` `.xls`
`.pdf` `.jpg`

`.xml`

Glemser TECHNOLOGIES

SECURE SPL ON DEMAND PORTAL

2 Convert to SPL*

* ACA submissions are submitted in an XML format that is not SPL

3 Perform Quality Review

4 Return SPL to Sponsor

FDA

8 Receive Sponsor SPL R4 Files

`.doc` `.xml`

9 Review and Approve Submission

A Provide Feedback to Applicant

`.doc`