ThinSpring

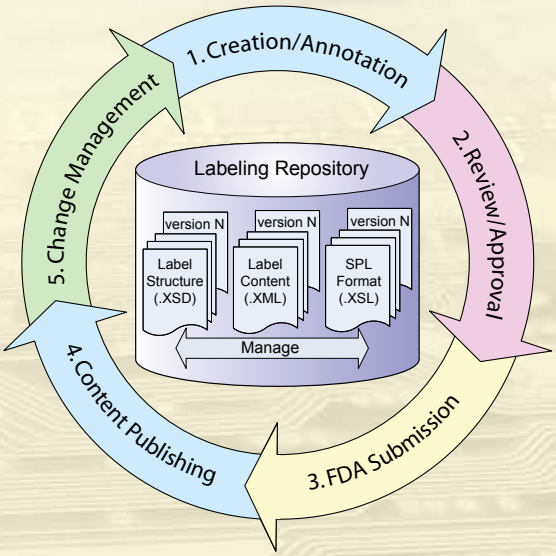
SPL Server™

Truly Web-Based, Browser Only SPL Compliance Solution

Create SPL with a Native Structured Content Authoring Tool and Full Submission Life Cycle Management Capabilities

Allow your regulatory operations staff, graphics designers and scientists to collaborate in real time when creating and maintaining labeling content. Whether they use a Macintosh or PC, no new software is required on the end user's work station. Only a browser is required to access all features and functions including native structured content authoring and document management. There is also an optional Microsoft Word interface that can be used to author content.

SPL Labeling Process



Key Features

- **Copy & Paste from Microsoft Word or PDF Content of Labeling Files**
- Clone files and products for data reuse
- Concurrent user authoring confguration management control - speed the authoring process!
- Full SPL native table editing
- Edit SPL content by section
- Add footnotes and footnote references
- Internal hyperlinking capability
- Import directly from DailyMed
- Realtime link to NDC Directory
- Validation errors point to suggested solutions and links
- Administer UNII
- Automatic Conversion to PLR human prescription label with highlights
- Knowledge management tightly integrated with SPL Server
- 'Smart' Active ingredient and moiety UNII validation and look-up
- Optional ESG interface
- Parallel Submission Management Version Control
- Image Management and Reuse
- Fully web-based, no browser plug-in or add-on is required

Ready for the Electronic Listing and Registration Challenge

Bound by federal mandate, the United States Food and Drug Administration (FDA) has required that all NDAs, BLAs, and Efficacy Supplements submitted after June 30, 2006 conform to the SPL-PLR rule. In addition, all companines regulated by The FDA Center for Drug Evaluation and Research (CDER) must register their facilities and list their products using SPL. This includes all Over the Counter products. ThinSpring products and services

are designed for complete compliance with the current SPL requirements. In addition, we provide Electronic Submission Service Gateway (ESG) services, submitting SPL files on your behalf and tracking them through the FDA publication process. ESG electronic receipt information can be tied to the SPL file submitted, providing a complete audit trail for your submission files.

Designed for Ease of Use

Regardless of your role in the labeling life cycle, SPL Server allows you to access the most important labeling information and tasks with the fewest number of mouse clicks possible. You can easily view and manage multiple "in-process" new submissions, supplements and changes in real time. Automatic notifications and alerts identify critical path items and help you stay on top of your regulatory operations work load.

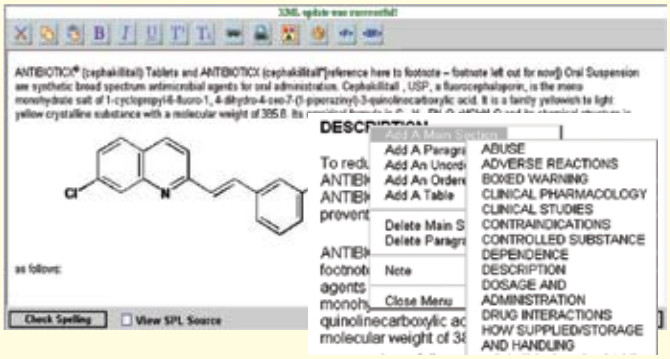
Tier One and Tier Two Validations Are Key

No SPL document will be submitted to the National Library of Medicine (NLM) if it does not pass the tier one and tier two validations. Tier one validation checks the SPL document against the latest HL7 SPL schema. If the document does not pass the tier one validation, the SPL will be rejected by the FDA before any review is even performed. We validate the SPL document against the HL7 standard SPL schema to verify the document will pass all schema validations when submitted to the ELIPS system. We also perform a tier two validation which enables you to see what the FDA will see once the label is submitted, therefore reducing the risk of a lengthy review process.

SPL Server Authoring Tool

Get real-time validation results with "What You See Is What You Get" (WYSIWYG) editing functionality. No need for additional training. Add and delete main sections, sub-sections, paragraphs, tables, lists, and notes from a consistent interface with the native structured data authoring tool.

SPL Server Authoring Tool



Indication and Usage (Updated for PLR)

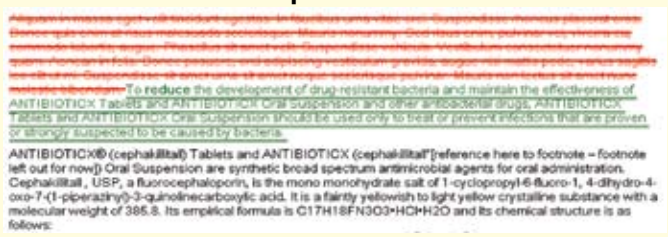
The indication and usage area has been extensively updated to include organization, information, and data entry for compliance with the Physician Labeling Rule (PLR).

Indication and Usage Screen

Compare Two SPL Versions

SPL Server takes the guess work out of labeling changes. With our compare functionality you can view differences in any two versions of a label.

Compare Screen


To reduce the development of drug-resistant bacteria and maintain the effectiveness of ANTIBIOTICX Tablets and ANTIBIOTICX Oral Suspension and other antibacterial drugs, ANTIBIOTICX Tablets and ANTIBIOTICX Oral Suspension should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

ANTIBIOTICX® (cephalkillital) Tablets and ANTIBIOTICX (cephalkillital)[reference here to footnote – footnote left out for now]) Oral Suspension are synthetic broad spectrum antimicrobial agents for oral administration. Cephalkillital , USP, a fluorocephaloporin, is the mono monohydrate salt of 1-cyclopropyl-6 fluoro-1, 4-dihydro-4-oxo-7-(1-piperazinyl)-3-quinolinecarboxylic acid. It is a faintly yellowish to light yellow crystalline substance with a molecular weight of 385.8. Its empirical formula is C17H18FN3O3•HCl•H2O and its chemical structure is as follows:

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