



ThinSpring



Quadrant

eLabeling Services

SPL-PLR Conversion Services

Are You Ready For The SPL Physician Labeling Rule (PLR) Challenge?

With The ThinSpring Team, You Will Be Ready For PLR

The addition of the PLR requirements to the SPL submission represents the first major change in the insert labeling in 25 years. PLR is intended to give health care professionals clear and concise prescribing information, better manage the risks of medication use and reduce medical errors, and make prescription information more accessible for use with electronic prescribing tools and other electronic information resources.

Federally Mandated PLR Requirements

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 NDAs, BLAs, and Efficacy Supplements approved since June 30, 2001 must be converted to the SPL-PLR format in the course of a 7-year implementation window.

What's New With PLR?

Some new elements have been added as a result of the PLR mandate including the Highlight Text section, table of contents, expanded codes, more medical terms, more reference tables, appended patient labeling, and Full Prescribing Information (FPI). All of the ThinSpring Team software and services are designed for complete compliance with the new SPL-PLR requirements. In addition, we've partnered with specialists Quadrant eLabeling (QeL) to create the technically sophisticated Highlight Text section with Custom SOW Definition, FPI creation and verification, highlight codes, and FDA support through the examination and approval process.

Highlight Text Section

This new section is now the first section of the label. The Highlight Text represents the most important data summarized in an easy to read format. All interaction, adverse reaction, and other important data has been elevated to the top level for increased visibility. The text in the Highlight Text section represents portions of data from many other sections including warnings, precautions, recent major changes, adverse reactions, indications, proper usage, interactions, and contraindications. Also included in PLR requirements is manufacturer information including com-

Key Features

- Partnered with specialists QeL to create the technically sophisticated Highlight Text
- Custom SOW Definition
- Create and/or Verify FPI / Highlights Text / Highlights Codes
- FDA support through the examination and approval process
- Conform with new PLR requirements for NDAs, BLAs, and Efficacy Supplements
- Patient information, patient packaging inserts, and medguides
- Table of contents
- Full Prescribing Information (FPI)
- Expanded codes, terms, and reference tables

pany, contact information for reporting adverse reactions, and year of initial US approval. This section is extremely sophisticated and requires very skilled knowledge to craft the needed text, coding, and medical terminology.

Appended Patient Labeling

Starting on June 30, 2007, all FDA-approved patient labeling (Patient Information, Patient Packaging Inserts, MedGuides, etc.) are required to be included with, or accompany, the SPL labeling submission.

Expanded Codes, Terms, and Reference Tables

There are some new NCI Thesaurus Codes and new LOINC Codes available for pharmacokinetic (PK) effect, consequences, medical problems, conditions, sex, and race. There are also new coding tables and terms from the United States Department of Veterans Affairs including drug class (VA NDF-RT), mechanism of action (VA NDF-RT MoA), physiologic effect (VA NDF-RT PE), and structural class (VA NDF-RT). The FDA has added a requirement that ingredients use FDA Substance Registration System (SRS) and Unique Ingredient Identifier (UNII). The FDA also extended the product information to include FDA Drug Registration, Listing System (DRLS) National Drug Code Directory (NDC), and National Drug File-Reference Terminology (NDF-RT).

Reed Technology, a ThinSpring Team Member

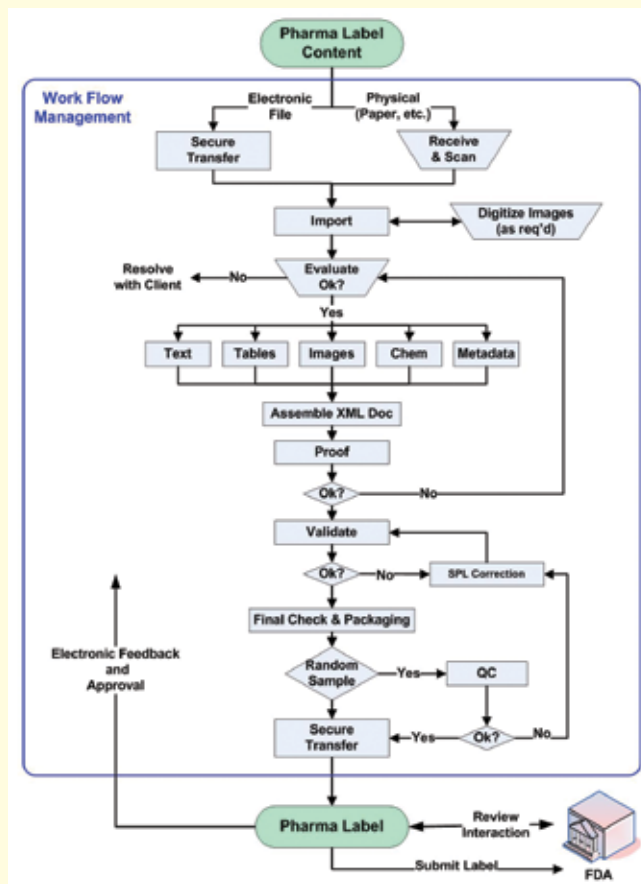
The ThinSpring Team member responsible for conversion processing is Reed Technology and Information Services Inc. Reed Tech is a leading provider of SPL and SPL-PLR conversions as well as Content of Labeling life cycle management. Three of the five largest worldwide pharmas, with hundreds of labels each, as well as many smaller pharmas, some with just a single label, rely on Reed Tech's high quality services to meet their SPL needs. Reed Tech has successfully converted over a thousand SPL labels to date. With ISO 9001:2000-certified processes, Reed Tech optimizes the balance between automation and manual intervention to ensure the highest degree of conversion efficiency and quality.

Quadrant eLabeling Services

Because of the high level of technical sophistication, only the most specialized and skilled technical experts can produce the Highlight Text section. Our partner, QeL, provides the solution by creating the Clinical Highlights Information for US Prescribing Information in the required PLR format. QeL also develops the medically appropriate conceptual data structure of the Highlights information, coding recommendations and options for client approval, and XML segments for inclusion in the SPL document by Reed Tech. The ThinSpring Team has become the top SPL-PLR Conversion provider by partnering with QeL to offer this capability.

SPL Conversion Services

Documents in any format are accepted for conversion.



The ThinSpring Team



ThinSpring



Quadrant

eLabeling Services

Contact Info:

991 US Highway 22, Suite 200
Bridgewater, NJ 08807
908-595-2145

© 2007 by The ThinSpring Team. All rights reserved. ThinSpring and the ThinSpring logo, Reed Tech and the Reed Tech logo, and Quadrant eLabeling and the Quadrant eLabeling logo are trademarks of their respective companies. All other trademarks are the property of their respective owners. Although the ThinSpring Team strives for accuracy in all its publications, this material may contain errors or omissions and is subject to change without notice. This material is provided as is and without any express or implied warranties, including merchantability, fitness for a particular purpose and non-infringement. The ThinSpring Team shall not be liable for any special, indirect, incidental or consequential damages as a result of its use.

Online Info:

www.thinspring.com
www.reedtech.com
www.qelabeling.com