



## pharmaceutical client

# Structured Product Labeling

### solution overview

**industry**  
Pharmaceutical

**challenge**  
To implement Structured Product Labeling (SPL) for a Pharmaceutical client within the scope of their existing enterprise content management system for electronic exchange of data.

**solution**  
Create smooth transitions from existing methods to SPL for the electronic submissions of various human pharmaceutical products. The implementation was a validated system.

**result**  
Helping our client meet FDA requirements by submitting internally approved US package inserts in SPL format to the Agency.

### overview

To Improve Patient Care and support health information management technologies, the Food and Drug Administration (FDA) adopted a Health Level Seven (HL7) standard for the electronic submissions of the content of labeling. In order to rapidly implement the standard, Technology Services Group assisted a Fortune 500 pharmaceutical client to integrate Structured Product Labeling (SPL) into their existing Documentum system. The solution was designed to facilitate the business processes to migrate from fixed print package inserts for human pharmaceutical products to leveraging the dynamic and powerful XML technology used in the SPL specification. Additionally, Technology Services Group helped our client select and manage relationships with their selected conversion and third-party software vendors.

### solution

The existing Documentum content management system using the Webtop interface was enhanced to accommodate:

- **Doctypes** - New doctypes for SPL documents, referenced images, and supporting documentation
- **Folder Structure** - A unique folder structure to make documents intuitively accessible to users
- **Import** - A seamless import process that would save components of an SPL document into virtual documents
- **Workflows** - Installed workflow templates that facilitated the electronic approval of a SPL file between multiple departments
- **XML Editor** - Integration of an XML editing tool that would be used to create new SPL documents, allow insertion of images that resided within the docbase, validate SPL documents based on FDA schema, and prepare a complaint submission

### result

The resulting internal enterprise document repository system was delivered in compliance with CFR Part 11 requirements. This was the first validated electronic system in the industry to handle the creation, management, and electronic approval of SPL formatted documents. With a system in place to facilitate the emergence of SPL, Technology Services Group helped transition our client from a concept of fixed print format to utilizing an extensible, scalable technology to submit SPL package inserts to the FDA upon the required effective date.

### contact information

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