

Solution for Structured Product Labeling (SPL)

An integrated labeling solution for the life sciences industry from Glemser and EMC

The Big Picture

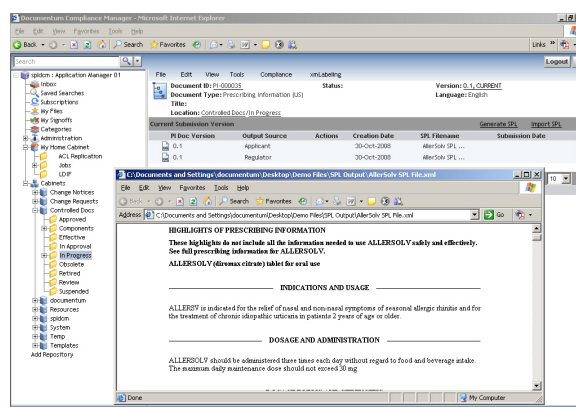
- Ensure compliance with SPL Release 4 requirements
- Generate a complete SPL Release 4 electronic submission file
- Improve efficiency by reducing the time required to create, review, approve, and manage product labeling documents
- Reduce costs by leveraging the DCM application environment
- Increase productivity by replacing manual procedures with automated workflows and electronic approvals
- Manage content in an agency-neutral format to improve content reuse, ensure compliance with evolving regulations, and simplify user training and support requirements

In 2005, the Food and Drug Administration (FDA) implemented a new requirement that human prescription drug manufacturers submit labeling content in an XML format called Structured Product Labeling (SPL). Since then, the SPL standard has continued to evolve and the FDA has recently released version 4 (known as SPL R4). In June 2009, additional types of companies—such as manufacturers of over-the-counter, biologics, animal health, and medical device products—will be required to submit labeling documents in SPL R4 format. In addition, companies will be required to submit NDC Labeler Code Requests and Establishment Registrations in SPL R4 format. Given the complexities of deploying information technology solutions in regulated environments, life sciences companies must begin implementing a solution now in order to meet the June 2009 mandate.

The complexity of managing labeling content and processes

One specific type of regulated content revolves around product labeling documentation such as package inserts (PIs), summaries of product characteristics (SmPCs), and core data sheets (CDSs). Labeling documents must be managed throughout their entire lifecycle in a timely and error-proof manner. This includes managing versions that have been approved by the health authority, as well as managing the editing, review, and approval process for versions being prepared for submission. Each revision to a labeling document involves numerous editors and approvers who need to act in a choreographed business process, in compliance with applicable regulatory requirements relating to access controls, audit trails, and tracking annotations. With labeling content constantly changing—typically averaging two to three updates per year for every drug—a content management solution is critical.

In the past, product labeling documentation was submitted either on paper or various types of electronic files. Today, labeling content is submitted to the FDA in a standardized XML format. Specifically, pharmaceutical companies were required to start submitting human health drug labeling in SPL format to the FDA in 2005.



SPL for DCM simplifies management of labeling content to meet regulatory requirements

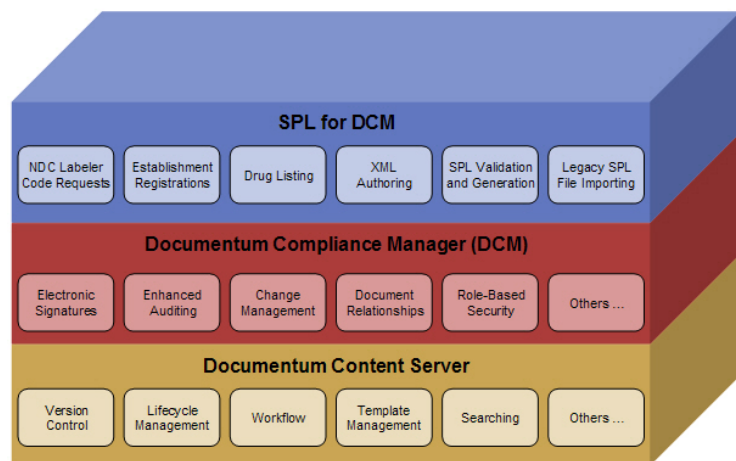
To address this requirement, some companies have used third-party conversion services or implemented internal processes to manually create and edit SPL files. While these approaches address the requirement, ultimately they add cost and complexity to an already expensive and complex process.

A better approach is to implement a content management system that directly addresses the business and regulatory requirements relating to labeling content. With this approach, companies can reduce cost and complexity by implementing a single system that manages the entire business process from document creation through submission. Process time is reduced, accuracy is improved, and compliance risk is effectively managed.

SPL for DCM: Out-of-the-box labeling solution

To help life sciences organizations comply with ever-increasing regulations, EMC and partner Glemser Technologies offer SPL for DCM—an out-of-the-box labeling solution based on the EMC® Documentum® Compliance Manager (DCM) application. The system provides a complete labeling content management solution and addresses the SPL R4 submission standard mandated by the FDA, as well as all relevant regulatory requirements for controlled content.

Built on the Documentum 6.5 platform, the SPL for DCM solution is implemented as a set of feature extensions and configurations of the DCM application. It is pre-configured to allow users to create and edit labeling documents such as package inserts and generate SPL submissions.



SPL for DCM provides new functionality while leveraging underlying DCM capabilities

SPL for DCM is the newest component in Glemser’s line of labeling solutions, which also includes xmLabeling®, the premier labeling content management solution available. In addition to SPL, xmLabeling supports the EMEA PIM standard and offers complete support for global labeling processes, including translations. Created to address the needs of companies who specifically need to comply only with the US-based SPL standard, the SPL for DCM solution can be easily upgraded to the full xmLabeling system if requirements expand to PIM and global use.

Specific features of SPL for DCM include:

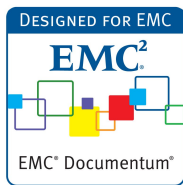
- Ability to create, edit, and manage content of labeling, drug listing, NDC labeler code requests, and establishment registrations in SPL R4 format
- Ability to import legacy SPL files into the content repository, automatically extract the drug listing information, and convert the textual content from SPL-specific to agency-neutral format
- Pre-configurations for US labeling document types in Physicians Labeling Rule (PLR) and non-PLR formats
- Automatic generation of SPL R4 from content managed in the DCM environment
- Seamless integration with either the Quark XpressAuthor or PTC® Arbortext® Epic XML editors for creation and editing of content
- A complete set of pre-configured document types and workflows that address labeling requirements

Glemser offers a complete set of installation, configuration, and validation services for SPL for DCM, which addresses the requirements of a full system lifecycle implementation. Designed for a twelve week project schedule, specific services offered in our Fast Path Deployment Program include:

- Requirements and analysis: A set of workshops to collect the requirements for the configuration of the system and introduce the application to the users
- System installation and configuration
- System testing
- Administrator training
- User training
- Validation services (optional)
- Data migration (optional)

A Designed for EMC accredited application

Glemser's xmLabeling solution carries the "Designed for EMC" accreditation. This accreditation ensures tight integration and product roadmap alignment between ISV applications and the EMC Documentum platform. Glemser's xmLabeling product is integrated and configured based on client's business processes and associated enterprise applications. Together, EMC Documentum and Glemser generate rapid return on investment, shortening time to deployment and replacing expensive customizations.



About EMC and partner content management solutions

This solution is one of many content management solutions offered by EMC and partners.

EMC and partners deliver content management solutions that help organizations to solve business problems specific to their function or industry. Built on the EMC Documentum platform, and combining EMC and partner technologies and services, these solutions help organizations to streamline and automate processes, increase productivity of teams and individuals, address their information compliance and retention requirements, foster creative work, and lower the cost of operations.



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.



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About EMC

EMC Corporation (NYSE: EMC) is the world's leading developer and provider of information infrastructure technology and solutions that enable organizations of all sizes to transform the way they compete and create value from their information. Information about EMC's products and services can be found at www.EMC.com.



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Take the next step

To learn more about implementing a Structured Product Labeling solution, visit www.EMC.com or call 800.607.9546 (outside the U.S.: +1.925.600.5802).