Datasheet : ALiCE for SPL

Key Features

- COTS software requiring minimal configuration to get started
- Familiar User Interfaces for fast user adoption – Microsoft Word and Web Browser
- Full 21CFR 11 Document Management support; Role-based Security, Document Versioning, Audit Trail
- Comprehensive Workflow/Life-cycle management (Draft, Review, Approve, Effective, Out-dated)
- Extensive SPL re-use between Labeler Code Request (LCR), Establishment Registration (ER) and Listing SPL's
- Integrated, automated, comprehensive submission validation
- Supports distributed labeling operations for registration and listing
- For SPL Authoring in Word features please refer to the **A4L** Professional Edition

Improving Accuracy & Efficiency

The FDA's SPL initiative continues to evolve and rollout at a rapid pace.

i4i's solutions support all SPL Release (R4 & R5) standards, and allows for the management of the complete authoring, review, validation, and submission process. Guided templates for creating and maintaining your Labeler Code and Establishment Registration SPLs, as well as for all product types, make SPL compliance easy.

ALiCE brings a comprehensive set of content management capabilities to support greater efficiency and accuracy to the creation and management of compliant SPL submissions and, to the broader processes in the organization that leverage the product/labeling information.

A Modular Approach

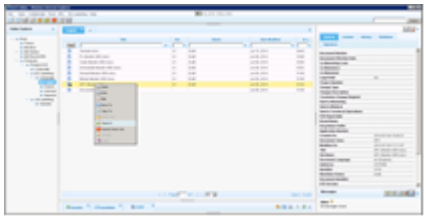
Integrated with i4i's market leading **A4L** Professional, **ALiCE** is modular in nature and highly configurable, with its capabilities delivered through an intuitive web browser interface.

ALiCE extends the authoring platform to bring key capabilities including document management, submission label management, and content reuse and repurposing.

Getting Started

The out-of-the box base module provides a fast and cost-effective entry point to the organization and management of in-process and submission–ready SPL documents;

- 21CFR11 Document Management (Role-based Security/Permissions, Document/Submission Versioning, Electronic Signatures, Audit Trail)
- Comprehensive & Configurable Document Lifecycle (Draft, Review, Approve, Effective)
- Source Document Relationships & Automatic Word Renditions
- Integrated Messaging – Alerts & Reminders
- Automated FDA Resource Updating & Submission Validation



ALiCE allows designated users appropriate access to all relevant workflow processes and management functions of **A4L**.

Roles of users and document status are configured to support existing internal processes and rules. Documents are checked-in and out, automatically versioned and, related to other documents through a simple web browser interface. Metadata (properties) such as brand name, dosage forms, active ingredients etc. are automatically extracted for easy access, discovery and workflow. The effective version of documents is always visible and its complete history available at the click of the mouse.

Registration, Listing and Content of Labeling activities can be done in parallel by different users/departments, supported by up-to-the-minute controlled vocabulary and UNII codes. All documents are then brought together and thoroughly validated for compliant submission publishing.

Throughout their lifecycles, Word renditions of SPLs can be automatically produced. Integrated messaging is used to support an efficient review and approval process.

Collaboration

The Collaborations Dashboard provides a single point of management for the key process of managing a complex parallel review process.

Using Word's familiar Track Changes feature; multiple copies of the document with editing and commenting can be merged into a single view for final review and approval.

The integrated messaging system assists in the efficient completion of the process.

Variant & Related Label Management

The management of multiple variants/branches of a document, necessary as new indications, formulations and adverse events trigger changes to content, is extremely challenging. Knowing the status of each document, and bringing the correct information together is the key.

The Variant Dashboard provides a comprehensive set of functions that allow you to initiate a 'branch' (a parallel version of a product label), substantiate it using a Change Request document, track and merge branches accurately, ensuring each new submission is fully compliant.

SPL Reuse & Repurposing

Creating structured content allows the SPL information to be easily reused and repurposed to support the accurate production of key related documents such as packaging, marketing documentation, Medication Guides and Patient Information.

Departments responsible for related documents can easily identify the currently effective version of labeling information and ensure that the content of all documents remains appropriately consistent.

Compliant SPL Documents

ALiCE offers extensive functionality for managing consistency and compliance.

The publish feature from the structured authoring application quickly and easily produces a compliant SPL submission package.

Managing final corporate and regulatory content and utilizing the content reuse and sharing features within **ALiCE** creates an efficient model to support the production of the SPL compliant documents for submission to the FDA.

Workflow, Metadata and Access

The workflow process in **ALiCE** is driven by metadata and can be easily configured to accommodate existing internal business processes and the rules associated with them. Reviewers access all server-side functions using the **ALiCE** Web Client interface. This includes features such as parallel review, document comparison, content reuse, translation management and management of different workflow states.

All security and access privileges are controlled at the individual, division or group level. As a user reviews and communicates with the sponsor, the submission becomes eligible for approval. Once approved, the submission's status changes and the document is automatically displayed to the labeling coordinator.

Support

Our investment in R&D ensures that the products you purchased continue to serve you as technology and regulatory requirements change.

i4i's Client Services Team consistently receives rave reviews for its responsiveness and the level of both product and regulatory support and guidance that is offered. When circumstances require additional resources, the team is pleased to offer outsourcing of registration and listing SPL's including gateway submission through our SPL DIRECT service.

Implementing ALiCE

The **A4L ALiCE** product series has been implemented at over 100 life sciences organisations in the US and Europe.

ALiCE can be licensed as a standalone solution or easily integrated with your existing corporate content management system; ensuring approved labeling content is available across your global organization. i4i's professional services team and our network of strategic partnerships will work with you to ensure a successful implementation in record time.

ALiCE is configured and tested at i4i and delivered to the client, ready to be installed, with supporting installation qualifications, making it fast and cost-effective to implement. The use of Microsoft Word and a Web Browser interface allows users to leverage current skill sets and rapidly become effective in all aspects of SPL authoring and submission management.

Contact i4i

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