i4i the structured content company

ALiCE for Global Labelling

Global Labelling Compliance with Structured Content & Data

Key Features

Intelligent structured authoring. With full Word+ experience.

Authoring applications include SPL, CCDS, EU QRDs & Product Information, CMC, Clinical…

Manages lifecycle of all documents.

Familiarity and ease-of-use of web browser Explorer and Microsoft Word.

Easily configurable.

Powerful dashboard process management.

Parallel review cycles by multiple reviewers.

Multi-document comparison.

Reuse and sharing of content.

Metadata driven processes. Automated, making workflow and authoring more intelligent.

Supports integration with external data sources.

Connectivity to document management systems (e.g., Documentum, SharePoint)

Translation management including support for integration with translation software.

Management of Global Labeling Submissions

With the adoption of XML technology, the FDA's SPL (Structured Product Labelling) and the EMA's xEVMPD and IDMP formats have triggered many changes in the label production process. To fully leverage the power of XML, i4i's ALiCE (Authoring Lifecycle Collaboration Environment) platform offers unique features that maximize the efficiency and consistency of the labelling process in ways that ultimately result in better compliant label content.

The Process

ALiCE is designed to manage the complete set of global labelling content. It addresses regulatory requirements and business processes that range from a single, authoritative view of product information to the exchange of objects between multiple authorities. ALiCE ensures consistency of all labelling documents across all related jurisdictions.

ALiCE's user interface combines work areas and dashboards into a single, intuitive view. Dashboards to manage document collaboration processes such as variants and translations can be configured according to user authority and need, enabling business-specific process and key interaction for specific authoring, publishing and validation functions.

Master QRD & Applicability

For EU submissions, it begins with the Product Definition Document containing general product and submission information, the product distribution structure [dose forms, strengths etc.] and defining the list of QRD instances to be produced.

A QRD Master is then created and maintained for each of the six QRD types. Any text shared across multiple QRD instances is maintained only once in the master QRD. Any text specific to a QRD instance is identified with an applicability attribute.

This organizational model uses the same source material to create documents for both the practitioner and the consumer. This allows the same information to be re-used, with each use specifically tailored for its target audience. Because the source

material for each of these uses is the same, this model easily maintains consistency of content across related documents.

The Functions of ALiCE

ALiCE offers extensive functionality for managing consistency and compliance.

IDMP READY
Ask us how IDMP fits into our Global Labeling Solution.
info@i4i.com

Label Document - Specific Views & Content Genealogy

i4i's structured authoring application allows authors and reviewers to view target documents directly from the integrated content model, the QRD Master. Views are selected and filtered based on the product definition and applicability for the QRD type and instance.

This product information model also captures the critical relationships of all content between documents. Using this unique feature of A4L, the user can easily investigate and understand the effects of any changes made to the content.

Translation Management

The unique integrated content features of ALiCE add tremendous value to the translation management process. For example, each QRD Master combines all European labelling content in a base language and removes all duplication of content as defined by the content reuse model. This single source of content for each QRD type can then be used for translation, thus reducing time, cost and errors in the translation process.

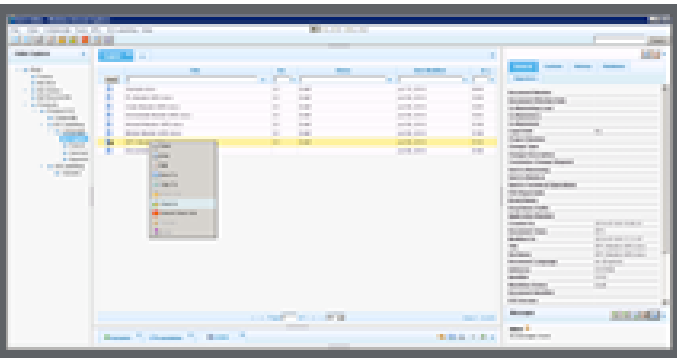
XML - Compliant SPL, QRD, XML PM & Other Jurisdiction-Specific Documents

The publish feature from the structured authoring application quickly and easily produces a compliant SPL submission package. Managing the multiple instances of each QRD type for a submission is more intricate and relies on the full ALiCE platform. Each QRD master provides a single source for all content on a product for that document type, and the publish feature in A4L allows for the creation of the specific documents from that source and generates a submission ready 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 any global regulatory documents with unique applications tailored for SPL and QRD-compliant documents for submission to the appropriate health authority.

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.



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

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 labelling coordinator.

Technology

Our Global Labelling functionality is the result of the customization and optimization of i4i's ALiCE technology for the Life Sciences industry. ALiCE uses a suite of specialized modules that hide all the complexities of the tasks and functions behind an easy-to-use web interface.

Implementing ALiCE

ALiCE can be licensed as a standalone solution or easily integrated with your existing corporate content management system; ensuring approved labelling 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.

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Contact i4i

For assistance using i4i products and tools, or for more information on technical support options, please contact:

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