A4L Enterprise for Global Labeling

Key Features

Intelligent structured authoring. With full Word+ experience.

Structured authoring of global labelling content and data including CCDS, SPL, XML PM, CCDS, EU QRDs, ePI , CMC.

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.

Content discoverability and reuse.

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

Translation management including support for integration with translation software.

RIM and external data source integration.

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

Management of Global Labeling Submissions

A4L Enterprise connects global content, controls complex document processes, tracks key lifecycle metrics, provides deep discoverability, relates and reuses content and data, within and across documents, and, supports existing and emerging global submission standards.

Achieve efficiency, auditability and compliance throughout the full lifecycle of your content.

The Process

A4L is designed to manage the complete set of global labelling content and data. 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. A4L ensures consistency of all labelling content across all related jurisdictions.

The A4L 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.

Structured Authoring & Reuse

Beginning with metadata-rich smart templates, content is authored and edited in MS Word, minimising training and increasing speed of user adoption.

Structured authoring templates adhere to strict compliance guidelines and utilize controlled vocabularies to ensure accurate and compliant content. The underlying semantic metadata makes content easy to track, control and analyse.

All content and data is addressable (“componentized”) and available to be used in and related across documents. To support unique characteristics of product information/labelling content a number of high value reuse models are built into the platform such as the PDD (Product Definition Document) and QRD Master for EU labelling. The PDD captures general product and submission information, the product distribution structure [dose forms, strengths etc.] and defines 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.

The Functions of ALiCE

ALiCE offers extensive functionality for managing consistency and compliance.

IDMP READY
Ask us how IDMP is fitting 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. Views are selected and filtered based on the product definition and applicability for the document 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.

Comprehensive Validaton & Publishing

A4L has a comprehensive readiness, validation and publish system that supports the creation of a submission ready package for all global jurisdictions.

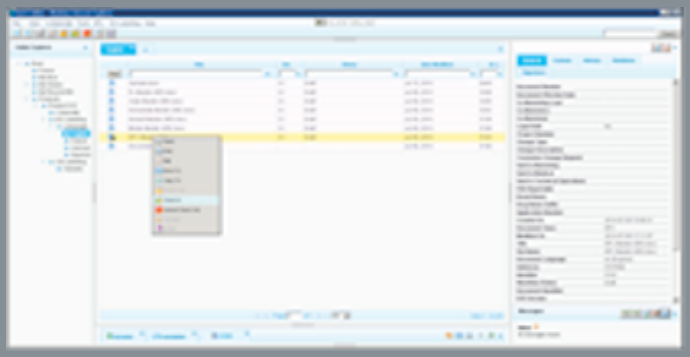
Your structured content within the system is easily adapted automatically to updated health authority requirements – including implementations of emerging and evolving standards such as SPL, XML PM, FHIR, ePI, IDMP etc.

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

Workflow 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 A4L 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 labelling coordinator.



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

Vision

Our vision is to create innovative structured content solutions to assist the life sciences industry with their product documentation and regulatory information management. We focus on developing applications that increase efficiency, consistency and support global compliance through innovative, cost-effective and reliable technologies.

Implementing A4L Enterprise

We've been doing this a long time, and it shows. A history dedicated to innovation and rich in accomplishment, along with industry-leading technology driving our platforms, our experience gives us confidence in handling all implementations with a proactive and professional approach. More importantly, we give you confidence that work will be done on time, on budget, and with results that deliver.

Contact i4i

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

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