



DATASHEET

A4L[®] – ALiCE for Global Labeling

Key Features

- Patented Microsoft Word Authoring solution
- Web interface
- Open Architecture for integration with external data sources
- COTS software requiring minimal configuration to get started
- SPL/PLR and PIM Validation & Lifecycle Management
- Change tracking, commenting, copy/paste from a Word document
- Structured Data and Narrative Text can be viewed and reviewed within the SPL document
- Section level editing
- Document comparison
- Multiple document formats (word, xml, pdf, graphics)
- Automated extraction of all metadata elements within the labels
- Parallel review cycles (concurrent edit/reviewing of labels - merging changes made by multiple reviewers back into one master xml file)
- Traditional document management (Check-in, Check-out, Check-out for review, Check-out exclusive, etc.)
- Integrated *aboutness* content models with built-in document relationships and content-reuse
- Audit trail of document history (status, and versioning)
- Identification of components each label uses (i.e. Image files, hyperlinks to sections, etc.)
- Section level control (ensuring only one person at a time can edit a section)
- Extensive content and document relationships captured automatically and used to determine the critical impact of required content changes

Authoring and Life Cycle Management of Global Labeling compliant submissions including SPL and PIM

i4i has found that new technology that improves key aspects of the label production process triggers business process changes that, ultimately, result in better labels. PIM (Product Information Management), and SPL (Structured Product Labeling), are technology triggers that can serve as the catalyst for positive change.

Both PIM and SPL use the widely accepted document encoding technology called XML, and since the days of MERS (Multiagency Electronic Regulatory Submission), the content management industry has been exploring how to use document encoding to improve document quality and process. Designed to leverage the power of XML, i4i's **A4L** platform offers unique capabilities that maximize the efficiency of content authoring and the consistency of the content across labeling documents (information agreement).

The Process

i4i's **A4L** product is designed to meet regulatory requirements and business processes, from production of a single, authoritative view of label content to the exchange of objects with competent authorities. Typically starting with a Company Core Data Sheet (CCDS) a European Labeling Master (EULM) document can be derived to begin the process of developing the full labeling content for European jurisdictions. This master content document can be enriched to support a complex content re-use model to maximize the efficiency of content authoring and the management of consistency across all labeling documents. From the EULM, individual QRD documents are derived

to initiate the content authoring process. These derived documents have unique life-cycles, inclusive of translations, of their own. The EULM, all derived documents, and any associated PIM submissions from this content are under version and process control managed by **A4L**.

A Single, Authoritative View of Label Content

The full global labeling content comprised of the CCDS, EULM, other jurisdictional labeling content such as the US SPL and, other corporate documents can be combined and reviewed through a unique master viewer, the 'Master Compliance Document (MCD).

Content Grouped by 'Aboutness'

The MCD and EULM XML organizational model is one that groups content by its *aboutness*; that is, content is organized not by the narrative flow requirements of a reader, but by the knowledge management requirements of an editor.

Storage and Handling Information	
Storage Warning (LM - Special Precautions for Storage) (Any, Any, Any)	The unopened bottle does not require any special storage conditions.
	After opening, the solution is chemically and physically stable for at least 24 hours at 2 to 8°C.
	From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C.
	Aclasta must be kept out of the reach and sight of children.
Storage Warning (SPC - Special Precautions for Storage) (Any, Any, Any)	The unopened bottle does not require any special storage conditions.
Storage Warning (Outer - Special Storage Conditions) (injection, solution, 5 mg, bottle)	The unopened bottle does not require any special storage conditions.
Storage Warning (Outer - Special Storage Conditions) (injection, solution, 5 mg, box)	None
Storage Warning (Outer - Special Storage Conditions) (injection, solution, 5 mg, carton)	None
Storage Warning (PL - Storing <product>) (Any, Any, Any)	Your doctor, pharmacist or nurse knows how to store Aclasta properly. See also the section "Information for the health care professional" at the end of this leaflet.
Storage Warning (CPI - Storing <product>) (Any, Any, Any)	
Reference to Immediate Container (LM - Nature and Contents of Container) (injection, solution, 5 mg, bottle)	Aclasta 5 mg/100 mL solution for infusion is supplied in a 100 mL transparent plastic



The objective of this organizational model is to facilitate the editor's ability to ensure consistency of meaning across document classes.

For instance, the SmPC, the outer label and the patient leaflet all have a *storage* section. Each of the label documents should say the same thing but in a different manner: the SmPC for the practitioner, the outer for the consumer in a very limited space, and the PL for the consumer in a consumer friendly manner.

Label Document Specific Views & Content Genealogy

Authors and reviewers often prefer to work with familiar documents i.e. an SmPC, CCDS, etc., the A4L Authoring component provides the capability to *derive* target documents directly from the integrated content models i.e. the EULM and the MCD.

Derivation is the process whereby the XML semantics in a source document, in this case the EULM, is mapped, in real-time, to the XML semantics of the target and the identified content copied into the target.

During the derivation process the identity of each source object and its resultant target object is kept as part of the history of the target. This audit information is used to map content changes in the target back to the source so that, for instance, if the <warning_s> content object is changed in an SmPC the A4L author knows which <warning_s> section in the EULM or MCD to update.

The derivation process captures the critical relationships of all content between documents. This information holds the key to A4L's unique ability to investigate and understand the effect of any historic or required change to content.

Content Efficiency & Reuse

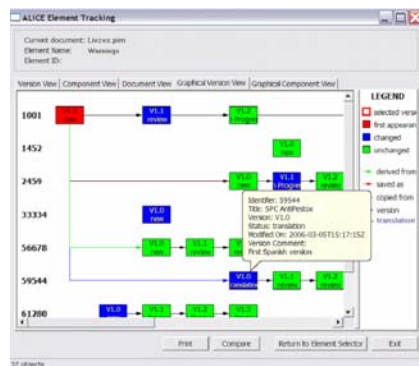
In addition to its standard services, the A4L Author supports two specialized services for content efficiency and reuse. The first service allows the user to define as well as use, content fragments stored and managed by A4L. This service allows a user to browse an inventory of for instance,

<pharmacological properties> content fragments for inclusion in the current document. Fragment default behavior in the including document is 'read only', ensuring that the approved <pharmacological properties> content is not modified. However, if the user needs to modify the content he can deactivate the link to the fragment and make modifications as necessary.

The second service allows the user to reuse internal document content by creating a reuse link between the source and the target. When the source is updated the target is automatically updated. For instance, if a table in the <indication_s> section is reused in the <indication_p> section the user can create a content reuse link between the two. If an exchange with a competent authority results in a change to the table, the change is automatically reflected in both places.

Translation Management

The unique integrated content features of the A4L solution add tremendous value to the translation management process. For example, the EULM combines all European labeling content in a base language and removes all duplication of content as defined by the content reuse model. A content source, now complete and significantly minimized in size, is available for translation, reducing time, cost and errors of the translation process.



Element Tracking allows users to quickly see where changes have been made, and what content needs to be updated.





XML Compliant PIM, SPL & Other Jurisdiction Specific Documents

The MCD satisfies the need for a single authoritative view of all content for a product, and the A4L author's derivation capability satisfies the need to create specific documents from the MCD. The A4L author's capability to share and reuse external content fragments as well as identify internal content objects for internal reuse satisfies the reuse requirement.

The final corporate and regulatory requirement is support for the production of PIM and SPL documents.

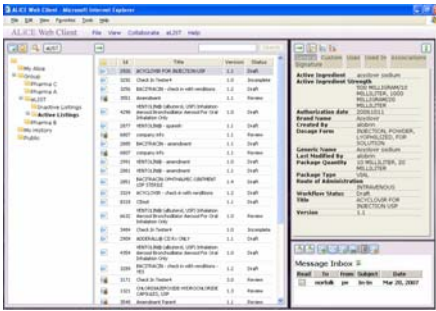
Workflow, Metadata and Access

The workflow process in A4L can easily be configured to accommodate existing internal business processes and the rules associated with them.

A4L allows reviewers to access all server side functionality (parallel review, check-in/out, merge, compare, approve, etc.) through the Internet Explorer "ALiCE Web Client" Interface.

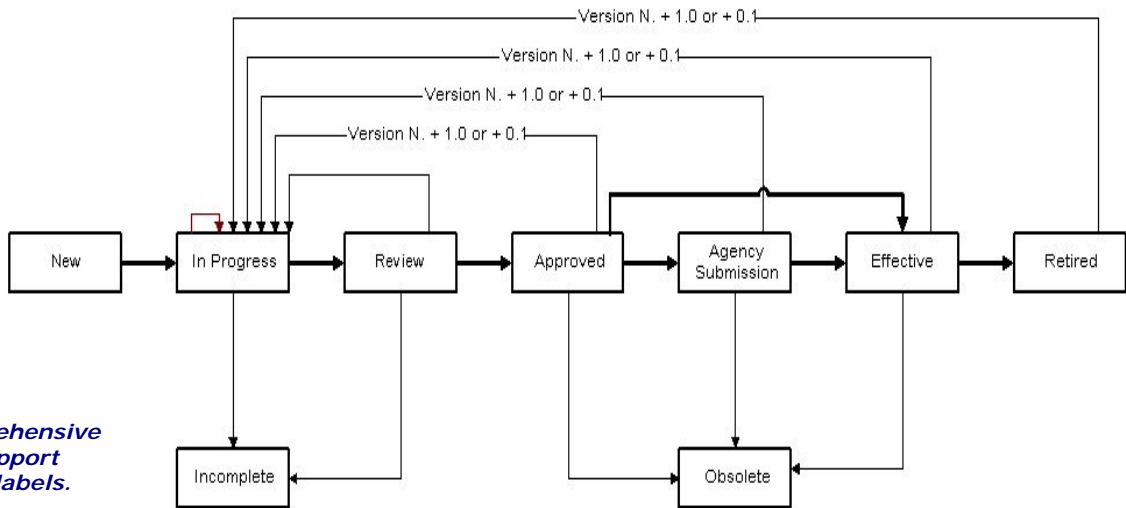
The metadata server transparently extracts data entered in structured sections and property dialogs of the XML documents and employs it to help the user organize structure and classify their work.

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 (status is another one of the metadata elements). Once approved, the submission's "status" metadata value has been changed and could now appear in a Labeling coordinator's "to-do" folder automatically.



The ALiCE Web Client allows designated users full access to all workflow processes and management functions of A4L.

LifeCycle in the Alice Global Labeling Solution



A4L provides a comprehensive workflow model to support the lifecycle of your labels.





A4L

Reducing risk by ensuring consistency and accuracy of your global labelling content.

Technology

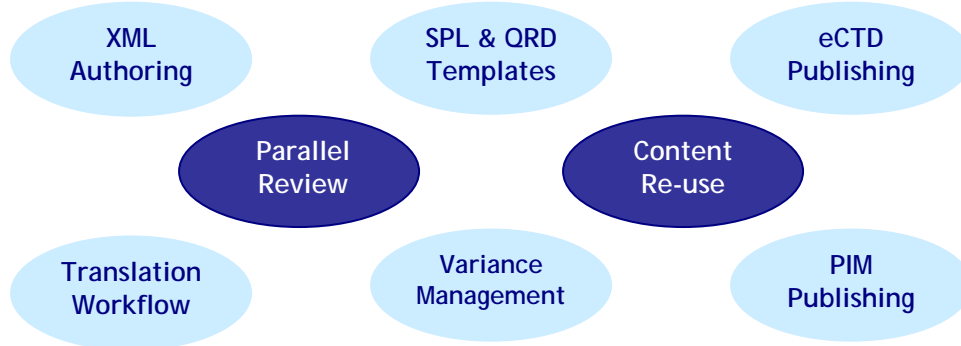
Behind the A4L Global Labeling Platform is a sophisticated collection of software tools. Authoring and review is managed by **x4o**®, i4i's patented Microsoft Word based XML editor. Access control, versioning, content collaboration and, SPL fragment management is provided by **ALiCE**, i4i's Authoring Lifecycle Collaboration Environment, a suite of specialized J2EE Web services modules that hide all the complexities of these tasks behind Internet Explorer. A4L can be easily integrated with leading ECMS systems to ensure approved labeling content is available across your global organization. All the tools use the industry standard XML protocols HTTP/WebDAV and SOAP making them fully interoperable with other Web applications and services.

Integration

A4L can be licensed as a stand alone solution or easily integrated with your existing Documentum, or other Corporate Content System through a standard ECMS Connector.

Implementing A4L

i4i's professional services team and our network of strategic partnerships will work with you to ensure a successful implementation in record time.



A4L – ALiCE For Labeling

i4i's Authoring Lifecycle Collaboration Environment



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