A4L Enterprise for XML PM

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/Lifecycle management (Draft, Review, Approve, Effective, Out-dated)

Robust management of key business processes, including Translations and Variants

Integrated, automated, comprehensive submission validation

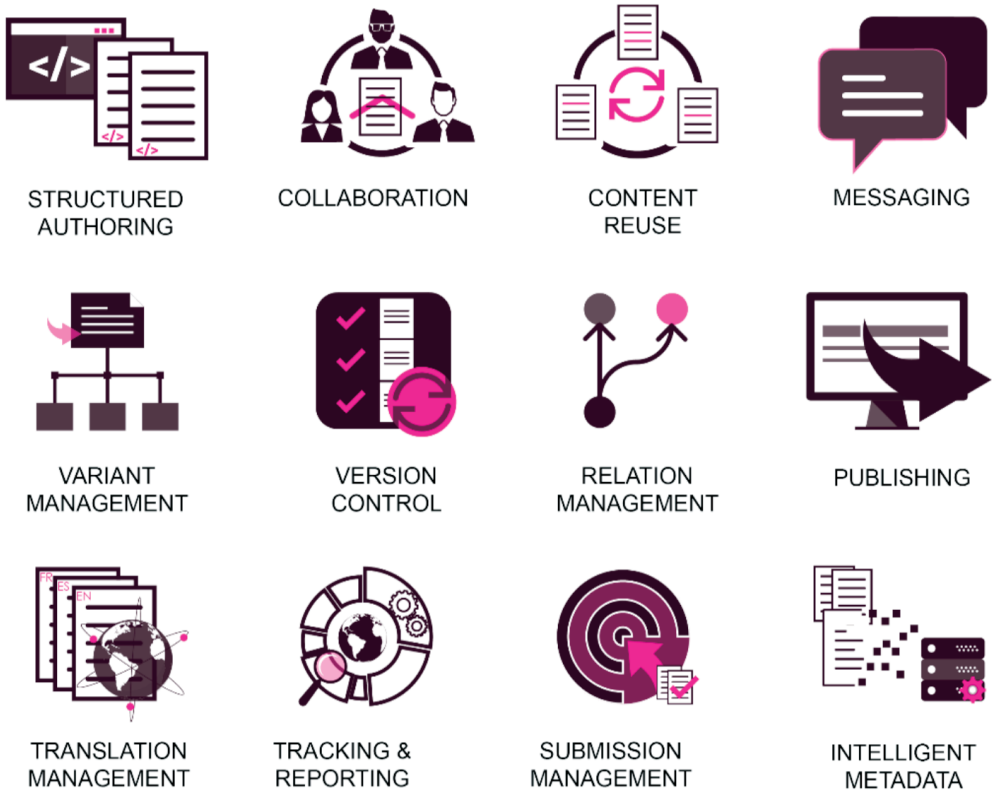
For XML PM Authoring in Word features, please refer to the A4L Professional Edition

Improving Accuracy & Efficiency

Health Canada's XML PM initiative continues to evolve and roll out at a rapid pace.

i4i's solutions support the management of the complete authoring, review, validation, and submission process. Guided templates for creating and maintaining your pharmaceuticals, radiopharmaceuticals, and biologics Product Monographs make 2020 PM and XML PM compliance easy.

A4L Enterprise extends the Professional desktop authoring platform, bringing a comprehensive set of content management capabilities including workflow/lifecycle, collaboration, translation, and variants through process management dashboards to support greater efficiency and accuracy in creating and managing compliant XML PM submissions.



Process Management

The authored structured content is rich with metadata that feeds key areas of process management. Translations, Variants, Relations, and Collaboration management dashboards drive and support both the highly linear and the complex parallel processes found throughout the labelling process.

Our dashboards support the who, what, when, where, and why of your content—capturing key metrics through its lifecycle for full tracking and auditability. The underlying semantic metadata makes content easy to track, control and perform cross-document and cross-jurisdictional content analysis.

Workflow, Metadata, and Access

The workflow process 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 Web Client interface.

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

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Translation Management

There are numerous benefits to structure when it comes to translation management, especially for Health Canada's English and French XML PM documents. For example, when you have authored one language of your document, let's say in English, you can then create and relate the other language document to it within the system. This relationship aids in synchronizing and managing the documents.

A4L Enterprise offers extensive functionality for managing consistency and compliance.

The Translation Dashboard provides a complete set of functions that allow you to create translation documents by automatically translating the values from the authorized controlled vocabularies. You can copy the metadata from one language version to the other and verify that the metadata of the language versions is in alignment. The dashboard sends reminders to submit translated versions within a deadline. Additionally, one of the most significant benefits is content alignment—making sure that all updates made to the first language document are included in the other language document. Content alignment can also include flagging new sections that are added to one language and not the other.

Variant 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. The key is knowing the status of each document and bringing the correct information together.

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

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.

A4L Enterprise is easily extensible to full FDA SPL Registration and Listing support, Corporate/CCDS, Global jurisdictions (EU, Japan. ROW) & Global Standards (e.g. IDMP) documents and submissions.

Compliant XML PM Submissions

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

Managing final corporate and regulatory content and utilizing the content reuse and sharing features creates an efficient model to support the production of the XML PM compliant documents for submission to Health Canada.

Getting Started

The out-of-the-box base solution for a single jurisdiction provides a fast and cost-effective entry point to the organization and management of in-process and submission-ready 2020 and XML PM documents:

- 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.

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 provide outsourcing of XML PM submission preparation.

Implementing A4L Enterprise

The A4L product series has been implemented at over 100 life sciences organizations in Canada, the United States, and Europe. A4L 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.

A4L Enterprise 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 XML PM authoring and submission management.

Contact i4i

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

Infrastructures for Information Inc.
720 King Street West, Suite 805
Toronto, ON Canada
M5V 2T3

Phone: +1 416.504.0141
Fax: +1 416.504.1785
Email: info@i4i.com
https://www.i4i.com