i4i the structured content company

i4i & Our Products

A4L Authoring, ALiCE, & Conversion Services Overview

a global platform to connect, control, track & analyse the content & data in your documents.

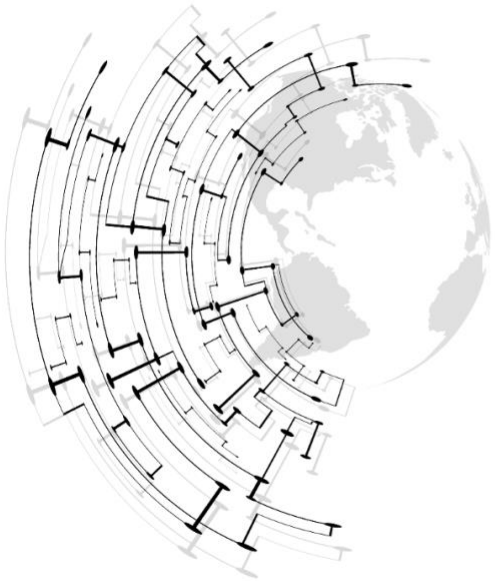
Our Story

i4i, an industry leader in the development of structured authoring technology in Microsoft® Word since 1993. We continue to innovate and evolve, producing new generations of our structured authoring solution.

Our A4L software preserves the complete Word authoring experience. Users can work within Word while authoring in a fully functional structured content authoring environment.

The intelligent structured authoring process is complemented by a simple and flexible repurposing function that enables publishing for any requirement – print, web, e-books, XML, etc.

An Industry Leader



25+
Years Developing Structured Content Technology

15+
Years Creating Solutions for the Life Sciences Industry

90+
Pharmaceutical Clients

Industry Leadership

- Key contributor to SPL Implementation Guide & XML standard
- Key contributor to Health Canada's XML PM Implementation
- HL7 SPL Working Group Leadership
- FDA SPL Working Group Member
- IRISS Member

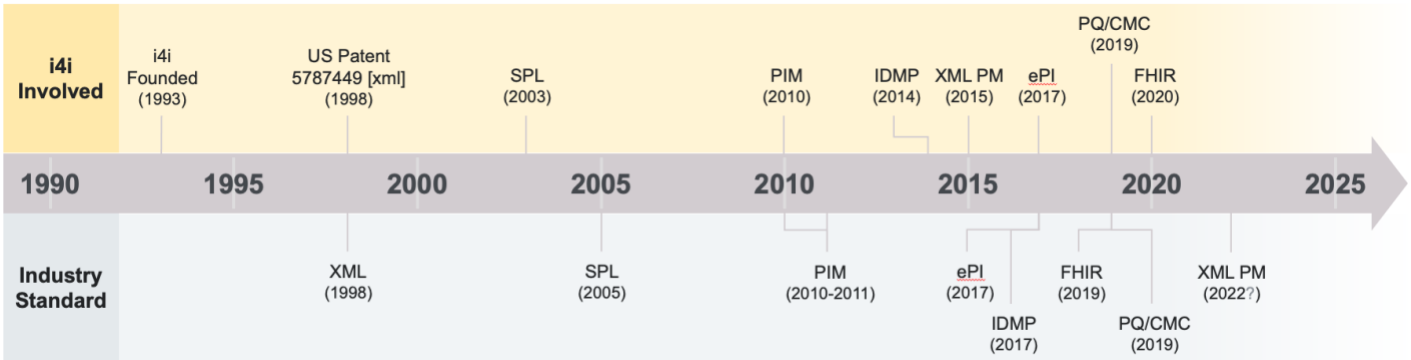
i4i's Expertise

Technology Expertise

- Structured content *(SGML, XML)*
- Structured content editor *(MS Word)*
- XML content management web services
- Infrastructure *(large/global deployments)*
- System integrations

Regulatory Expertise

- Application of technology to regulatory processes
- Support regulatory processes in 100+ jurisdictions
- Quality assurance / validation
- Continuously involved in regulatory industry, life sciences *(SPL HL7 Working group / XMLPM / IRISS / FHIR HL7 Vulcan Accelerator / etc.)*
- Cooperation with regulatory authorities *(FDA, Health Canada, EMA)*



Unique Solutions

Our primary software solutions are A4L Professional and A4L Enterprise with ALiCE.

These solutions use familiar interfaces that require no technical expertise to use, making them easy to adopt. Authoring and managing structured content is as easy as using plain MS Word. Our templates ensure that the structure of your labeling documents meet health authority requirements. And we offer multiple publishing options, document variant creation and management, and translation management where applicable.

We embrace regulatory standards including, but not limited to: SPL, IDMP, XML PM, etc.

Beyond our software, we offer our conversion services. Our regulatory specialists use A4L software tools to author and validate your documents and can submit them to the electronic submission gateway in the US and Canada on your behalf.

Want to talk to us about our solutions, reach out to info@i4i.com.

Our Software: A Closer Look

A4L Authoring Tool

A fully validated solution, available as a standalone desktop Authoring Solution or as a Global Platform and can easily be integrated with most existing corporate content management systems.

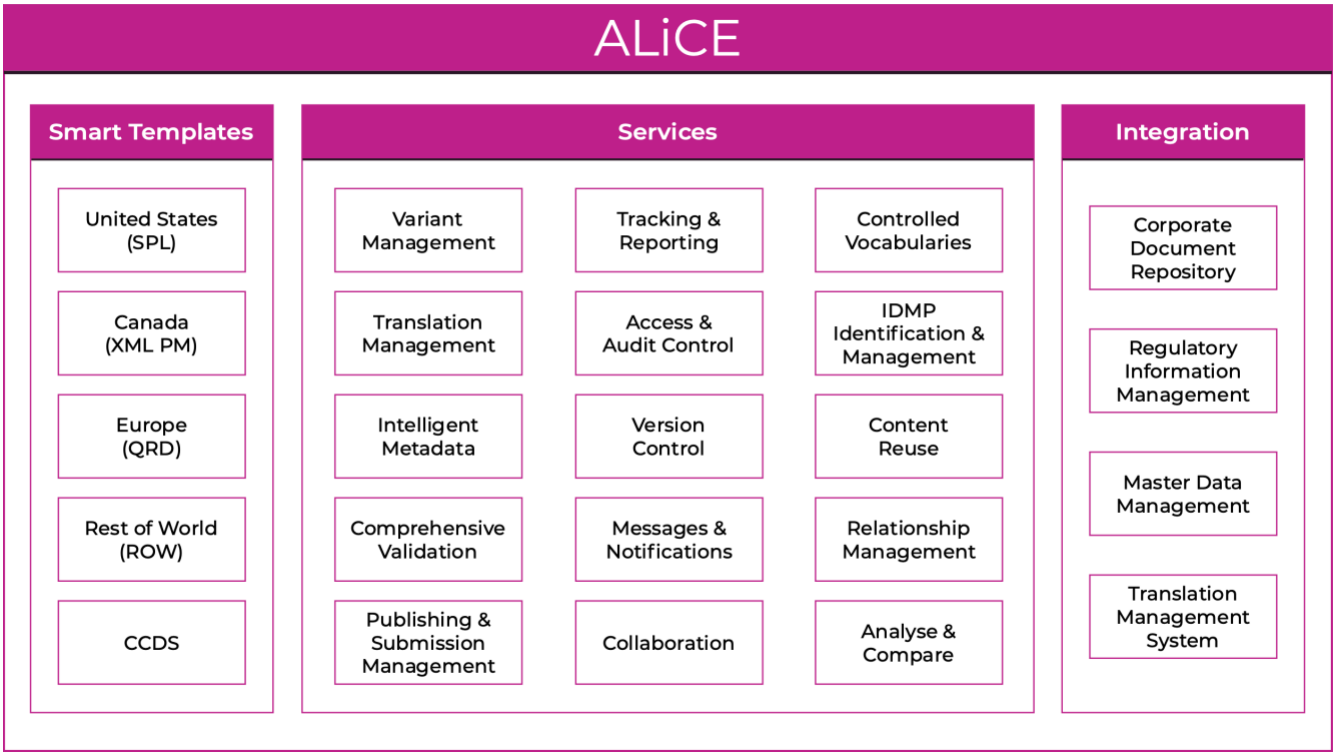
With a global labeling solution designed for the Life Sciences industry, A4L delivers intelligent structured authored applications with all of the functionality, flexibility, and extensibility of XML – all through the existing versions of Microsoft Word sitting on users' desktops. All XML is hidden from the users. They use only the tool they know – Word.

ALiCE Lifecycle Management

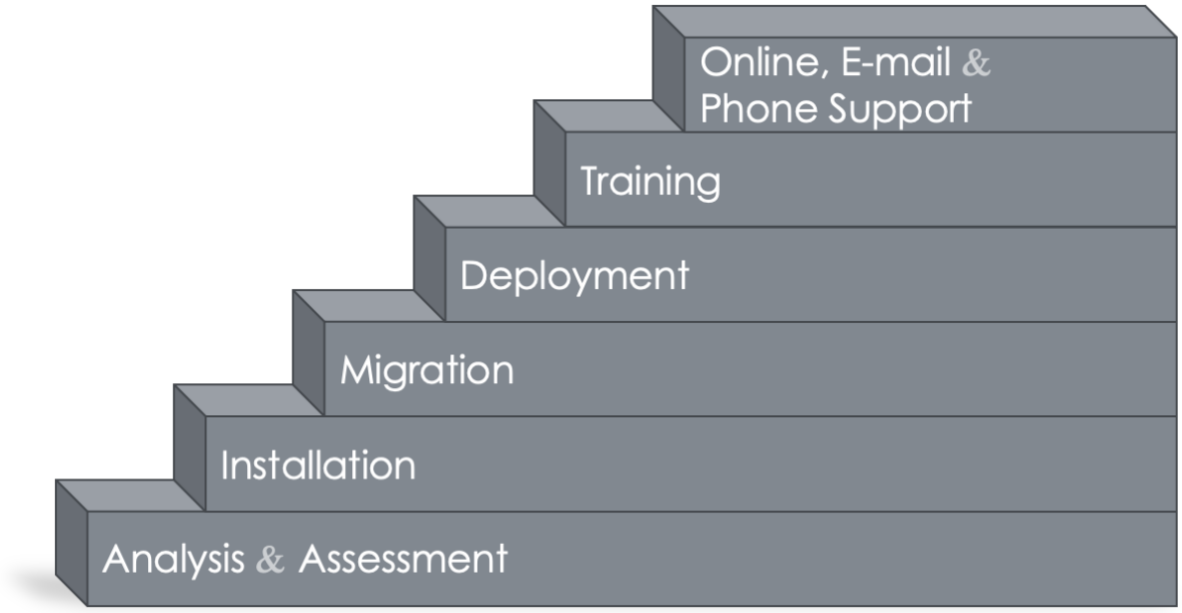
Our Life Sciences Global Solution expands our intelligent structured authoring tool with a robust suite of content creation, collaboration, tracking and management features for all your labeling and corporate document needs.

Designed specifically for the management of structured content. It provides full workflow, collaboration, and version control, using access control rules based on users, groups, roles, and permissions. A fully validated solution that easily fits within

your corporate technology environment. See the ALiCE (Authoring Lifestyle & Collaborative Environment) section below for further details.



Our Implementation Process



Regulated Content Challenges

Accuracy

- Manage change (tracking changes / genealogy)
- Version control (managing multiple revisions & approvals)
- Data alignment / synchronization
- Validating claims (linking supporting documents / reports)

Consistency

- Submissions for multiple HA (local regulatory information & requirements)
- Cross audience alignment
- Globalization (distribution & translation)

Compliance

- Globalization (localisation)
- Process & submission timelines in a competitive industry
- Regulatory alignment
- Discoverability / auditability

Intelligent Structured Content Advantage

Reuse/Repurpose: Structured content provides an easy way to *create content once* and reuse it in multiple documents and submissions and publish in different formats. Reduces duplication and time/cost of content processes (e.g. translation) – ensures *consistency & efficiency*

Structure & Standard: XML supports industry–specific data structures, easing compliance with regulatory requirements and information exchange standards - *guarantees longevity of content*

Discovery: Structured content is metadata & semantically rich for *discovery* and *analysis* – enabling cross audience content alignment and data synchronization

Machine processable: Structure drives *automation* of key business processes

Content is Tracked: At every point in the lifecycle, with strict *version control* creating full *auditability* / genealogy

Intelligent Structured Authoring

- Work in Microsoft® Word
- No XML to learn
- Structure, Standardization & Efficiency
- Validation rules to enforce authoring standards
- Repurpose content and publishing to multiple formats [web, pdf, word, artwork, XML…] and multiple outputs [USPI, MedGuide, brief summary, patient information…]
- Metadata-rich for data discovery
- Structured documents for all divisions and jurisdictions in an organisation, e.g. – CCDS, CMC, US SPL, XML PM, QRD, QUALITY, POLICY, PROCEDURE, LEGAL…
- Comply with the demands of regulatory agencies to meet quality and safety requirements during submission process
- Publish compliant regulatory submissions

Unique Features

Correct Typography: Utility to enforce style guide requirements for your documents, ensuring consistency

Glossary Manager: Allows users to tag terms throughout documents and add definitions in a Defined Terms section of a document – terms are automatically added to the glossary table

Taxonomy: Associate taxonomy terms with a selection of text

ALiCE (Authoring Lifestyle & Collaborative Environment)

Designed specifically for XML-aware content, ALiCE extends our first-in-class desktop solution into a powerful lifecycle management solution for all your product information, labeling, and corporate content.

A fully validated solution that easily fits within your corporate technology environment.

Key Terms: Regulatory Compliance, Corporate Standards, Reuse, Repurpose, Analysis & Discovery

Features

- Full lifecycle management
- Familiar, intuitive, browser interface
- Access control, process driven
- Metadata rich to drive content discovery
- Version control and change request management
- Publishing and submission management
- Internal messaging and notification system
- Audit control, reports, impact analysis
- Comprehensive validation
- Relations tracking
- Discussion panels / message boards

Featured Process Management

- CCDS
- Global Labeling
- Variants
- Translations
- IDMP

Content Management

Basics: Check in/out, Versioning, Audit trail, E-signature, 21 CFR Part 11, Workflow

Advanced: Content reuse, Collaboration , Translation management, Content tracking, Document relations, Impact analysis, Compliance monitoring, Integrated messaging, Alert management

Our Global Platform

- US SPL
- Canadian XML PM
- CCDS
- IDMP
- EU QRD
- Quality
- Policy & Procedure

Contacting 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
E-mail: support@i4i.com

https://www.i4i.com