Datasheet: A4L Professional Edition

Key Features

Microsoft® Word-based authoring

Multiple-file format rendering (word, xml, pdf, & graphics)

Automated FDA Resource Updater for validation rules, controlled terminology, and UNII codes

Comprehensive validation

Powerful "Word to XML" paste function

Legacy format to PLR migration support

Integrated lists of key terms, supporting fast and compliant submissions

Familiar Word environment ensures quick user adoption.

Extensible to the ALiCE Edition for features such as 21CFR labeling management, Variance, Parallel Review, Compare, Cross Document Re-use, and more

Prompt and knowledgeable support from services team

SPL DIRECT - outsourcing services

SPL Authoring & Submission Creation in Microsoft® Word

A4L Professional leverages i4i's industry leading Microsoft Word-based structured authoring platform, allowing users of all levels to easily manage the entire SPL authoring and collaboration process.

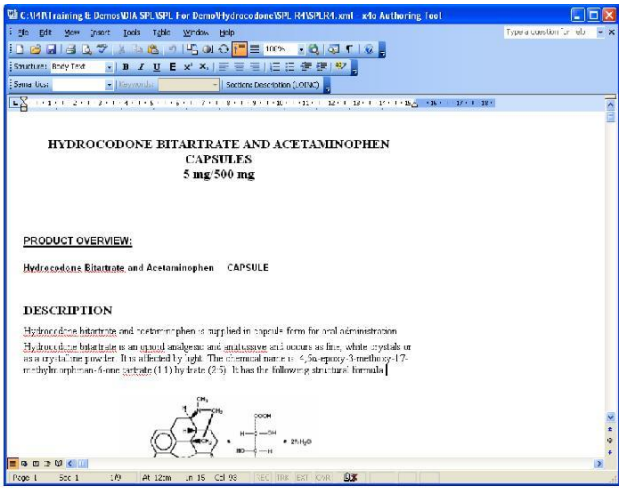
A4L simplifies the SPL authoring process by presenting the user with the familiar Word interface, as **A4L** works behind the scenes to create valid SPL submissions.

Comprehensive Regulatory Support

A4L supports all SPL Release (R4 & R5) standards, and allows for the management of the complete Authoring, Review, Validation, and Submission process. Guided templates for creating and maintaining your Labeler Code and Establishment Registration SPLs, as well as for all product types listed below, make SPL compliance easy:

- Human Prescription Drugs
- Over-The-Counter (OTC)
- Biological Products
- Cosmetics
- Dietary Supplements
- Veterinary Medicines & Medicated Feeds
- Bulk Ingredients/APIs
- Medical Foods
- Homeopathic Drugs
- Medical Devices

- Establishment Registration
- Labeler Code Request
- Generic Drug Facility Identification Submission
- Identification of CBER-Regulated Generic Drug Facility
- Lot Distribution Report
- Risk Evaluation and Mitigation Strategies (REMS)



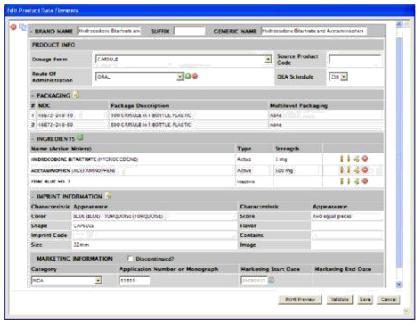
Coming soon: Human Compounded Drugs, Animal Compound Drug, Wholesale Drug Distributor / Third Party Logistics Facility Report

Ease of Content Migration

Migration of existing content is fast and easy. Content can be authored directly in the templates, or copied and pasted from other sources – thanks to **A4L**'s unparalleled "Word to XML" paste function. Even the most complex content, such as tables and graphics, are copied with ease into **A4L.**

The Physician's Labeling Rule

A Physician's Labeling Rule (PLR) formatted SPL can be easily created from scratch, or upgraded from an existing non-PLR document. Standardized sections and boiler-plate text are automatically generated, and Highlights are uniquely arranged to ensure content compliance with the related section's text. When converting a non-PLR label to the PLR format, **A4L** automatically reorders sections, and guides the user in the necessary content revisions to ensure compliance.



Forms integrated into Word lets the user easily complete all required listing information.

Automated Code Management

Everything involving the management of the GUIDs (Globally Unique Identifiers), XML attributes, Ingredient Codes (UNIIs), and coding associated with the FDA's controlled vocabulary is automatically handled within **A4L**. **A4L** takes all technical complexities out of the SPL process, allowing authors to focus on the content while easily creating valid and compliant submissions.

Validation ensures compliance during the authoring process.

Compliant Drug Listing

A4L features user-friendly forms that guide the user through the definition and population of all required drug listing information. Its unique FDA Resource Updater ensures the extensive lists of FDA-controlled vocabulary, within the **A4L** interface, remain current as changes are made by the FDA.

Extensive Validation

A4L features a comprehensive, built-in validation engine that ensures the content is complete, consistent, and compliant with the most current regulations. The validation in **A4L** incorporates all of the rules outlined in the FDA's Implementation Guide, the latest Validation Procedures, and the XML Schema.

Supporting Our Clients

i4i's investment in R&D ensures that **A4L** Professional continues to serve you as technology and regulatory requirements change. We also offer the opportunity to extend your solution, on a modular basis, to **ALiCE** (Authoring, Lifecycle and Collaborative Environment) – to support the broader labeling management issues such as versioning, change management, variance, and cross-departmental content "agreement". i4i's Client Services Team has gained recognition for the swift, high-quality product support and regulatory guidance that it provides. When circumstances require additional resources on your side, the team is pleased to offer outsourcing of all registration and listing SPLs, including gateway submission services.

Leadership

Since 2004, i4i has been a key member of the SPL Working Group, where we have used our XML knowledge and industry expertise to support the FDA's SPL initiative. We remain committed to delivering comprehensive and easy-to- use authoring and content management solutions that are first to market and best-in-class to comply with FDA standards.

Contact i4i

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