

A4L 5: An Introduction

*Authoring your content
using A4L 5.x*

■ Introduction

The A4L 5.x authoring tool combines the ease-of-use and familiarity of Microsoft® Word with the power of XML.¹ Whereas previous versions purposefully limited the user's access to those Word functions supported by the XML schema, A4L 5.0's default configuration removes those restrictions and supports the full Word experience.²

In 1998, i4i released the first version of its Word/XML authoring solution, based on its patented award-winning technology. This solution has since been used to create a variety of document types, including:

- Drug product labels
- Corporate & regulatory documents
- Legislative documents
- Technical documents
- Marketing materials
- ... (a list too long to enumerate here)

During this same period, XML has grown from a concept to the default format for the most widely used content creation tools (e.g., Word, Adobe's InDesign, and the open-source OpenOffice).

A4L 5.x Authoring Tool is the result of this confluence.

Note: A4L Authoring Tool is the authoring component of A4L, the lifecycle management solution for XML content, focused on drug product labeling.

■ Background

In the world of XML authoring, tradition dictates that the XML schema of the target output controls the authoring experience. In this model, the tag set supported in the XML authoring tool focuses on business tags: tags that identify the role of content in a document, in the context of a data-driven business process.

Presentation or technical tags are limited to the minimum required to publish the complete document. Therefore, if the business process or publishing process does not track changes, no tags for this are included in the schema.

Early on, i4i recognized the limitations of this model. Prior versions of A4L provided limited support for such tags, independent of the schema requirements. Overall, however, the implementation remained constrained by the traditional model.

■ XML Authoring: Everyone's Doing It

XML authoring is now mainstream. In fact, anyone working with Microsoft® Word since version 2007 is by definition “doing” XML. But this XML is limited to the presentation, or “look and feel”, of a document. It does not address the use of XML in a business context, such as that required for i4i's target business market: drug product labels.

In A4L 5.x, i4i uses lessons learned from over a decade of building business solutions to create the next generation of Word-based XML authoring.

The most important lesson learned, and applied, is that users want to preserve their Word experience. They do not want to be constrained by the limitations of a schema's tag set, or its view of the editorial process. Users want to do what they do—and bring the XML into play only when and where it is appropriate for the business process.

Users recognize the importance and role of business templates and want them to be unbreakable. But they do not want templates that, while unbreakable, are so inflexible that they make authoring cumbersome and the editorial process more complex.

■ A4L 5.x Authoring: Key Features

Moving to the Centre of the Process

With A4L 5.x, XML authoring moves from the tail end to the centre of the business.

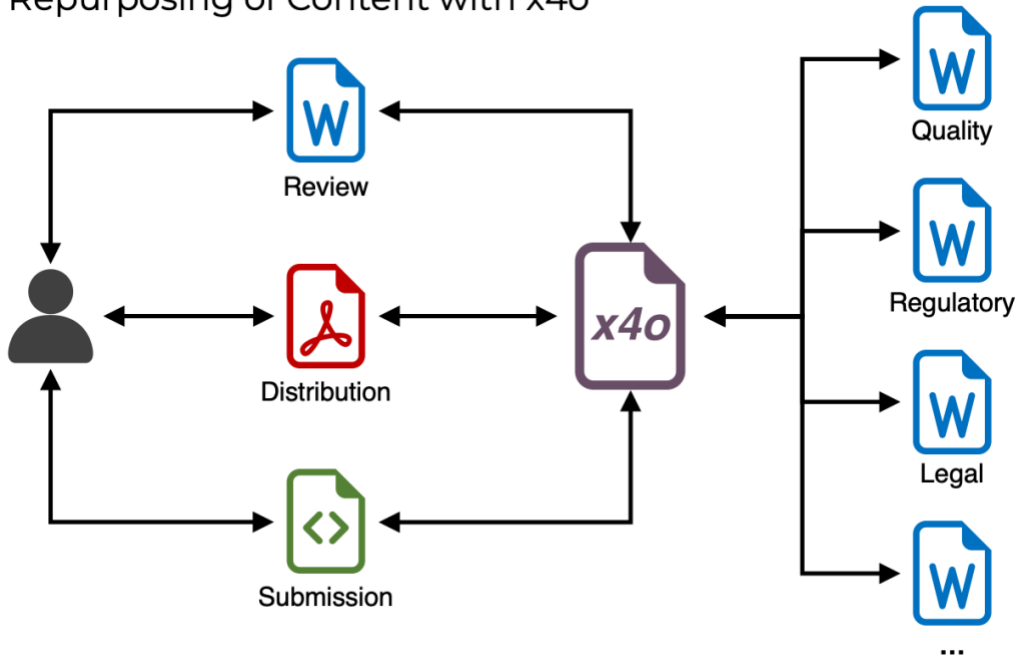
A4L is driven by XML-enabled Word templates. Consider the example of the US FDA's Structured Product Label requirement: i4i provides a complete inventory of Word templates that guide the user through the process of creating any type of SPL they need.

At any time in that process, the user can send their document to another Word user, including an FDA reviewer. The reviewer can open and work on the document, and then return it. With a few mouse clicks, the reviewer's work is incorporated into the working document as track changes.

The changes are accepted, and the exact same document is submitted in SPL XML to the FDA, or is transformed to PDF for general distribution.

Note: The same functionality applies when using European QRDs.

Repurposing of Content with x4o



Word Features

Virtually all Word features are now enabled by default, including:

- Track changes and commenting
- Table and list editors
- Footnotes, bibliography, and references
- Table of content and figures
- Equation editor
- Page layout

If needed, Word functions that are incompatible with corporate editorial practices can easily be turned off. This is achieved through the manipulation of a configuration file, meaning that the new configuration can be implemented without validation.

Regulatory Conformance (EMA/FDA): When You Need It

In addition to the QRD templates and IDMP forms, A4L 5.x includes templates for all SPL configurations (24 and counting), including:

- PLR to Vet products to OTCs
- Medical Devices
- Establishment Registration
- Product Listing

The templates are guides to help authors organize their content, and work to best practices for authoring drug product labels. Sometimes the work process requires that

users stray from best practices and use Word features such as text boxes, which are normally not allowed.

Rather than stopping the user from using important tools, A4L includes additional tools to check the document for things that are not allowed in the final XML regulatory submission. The user is warned that they are not allowed and, if the user chooses to keep them, they are preserved—they simply don't show up in the submission to the regulator.

This checking is done on demand and is an integral part of pre-submission validation.

Editorial Process Support

In addition to supporting Word's native track changes and commenting features, A4L 5.x includes additional functions to help with the editorial process.

Users can now distribute A4L documents to outside reviewers in Word or PDF format. If the document is distributed in Word format, any changes can be brought back to the A4L document as track changes. Comments are included as well. This lets the A4L user interact directly with the regulator, as well as other parts of the enterprise.

For complex processes where there are variants of a drug product label, A4L introduces the Annotation View. This view takes each paragraph in the document and places it in a table row, with one or more "annotation" cells next to it. Each reviewer can add their own annotation cells and content as needed. Alternatively, users can "drag and drop" content from variant documents into the cells, creating an easy-to-use, side-by-side view of the label document and its variants.

For "conversion" users, A4L continues to provide high quality copy and paste features—into the A4L label from PDF documents or other Word documents. A4L 5.x lets the more advanced user open an existing label document, which is not governed by an A4L SPL or QRD template, and "wrap" content with SPL or QRD section identifiers.

Conclusion

A4L 5.x Authoring Tool delivers on the reuse and repurpose promises of XML, while preserving what authors want most—their Word experience. Creating an SPL is no longer a tail end process, disconnected from day-to-day business processes.

Whether creating an SPL, QRD, regulatory content, or any corporate document, initiating a review in Word, A4L 5.x delivers on the XML promise.

Notes:

1. A4L 5.7.2 works with Word 2016 and higher. It also works with Microsoft 365 (with local installation of Word on a computer with Windows 10 or greater).
2. If necessary, A4L 5.7.2 can be configured to limit the Word experience in keeping with corporate policy.



Contacting i4i

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

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