

# Global Alignment

Managing Compliance Across  
Jurisdictions from Authoring to Submission



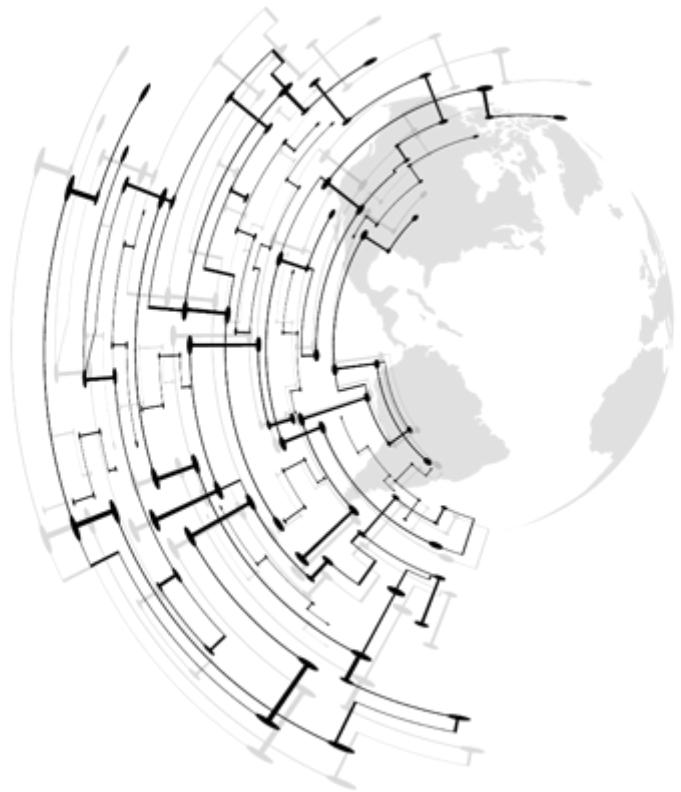
# Coffee Corner

## Join The Discussion

i4i welcomes you to our **Coffee Corner** presentation at this years DIA Annual Canadian Meeting.

Come and ask your questions about how Structured Labelling—especially for XML PM—can work for your documents.

# A Little Bit About Us



25+



Years Developing  
Structured Content  
Technology

15+



Years Creating  
Solutions for the Life  
Sciences Industry

90+

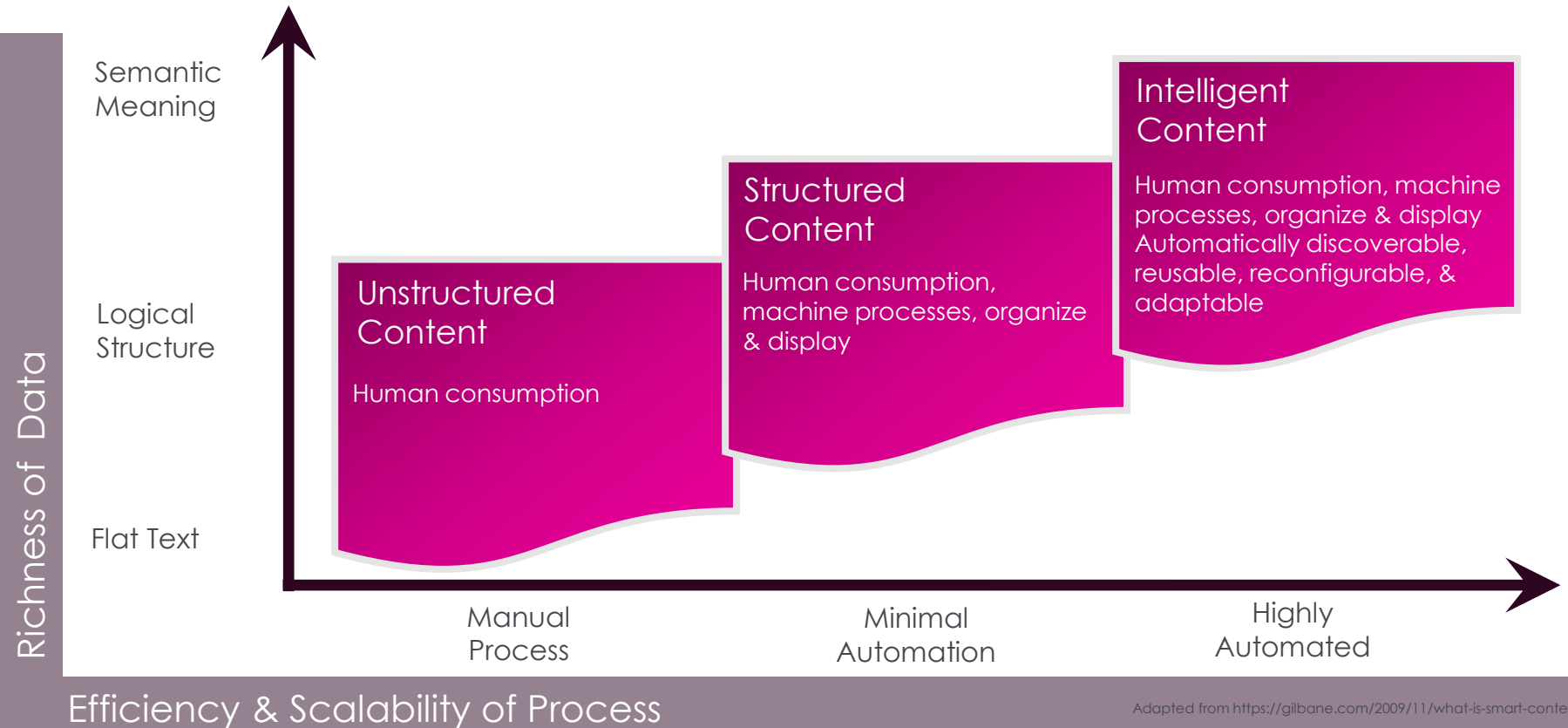


Pharmaceutical  
Clients

## 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

# The Evolution of Content

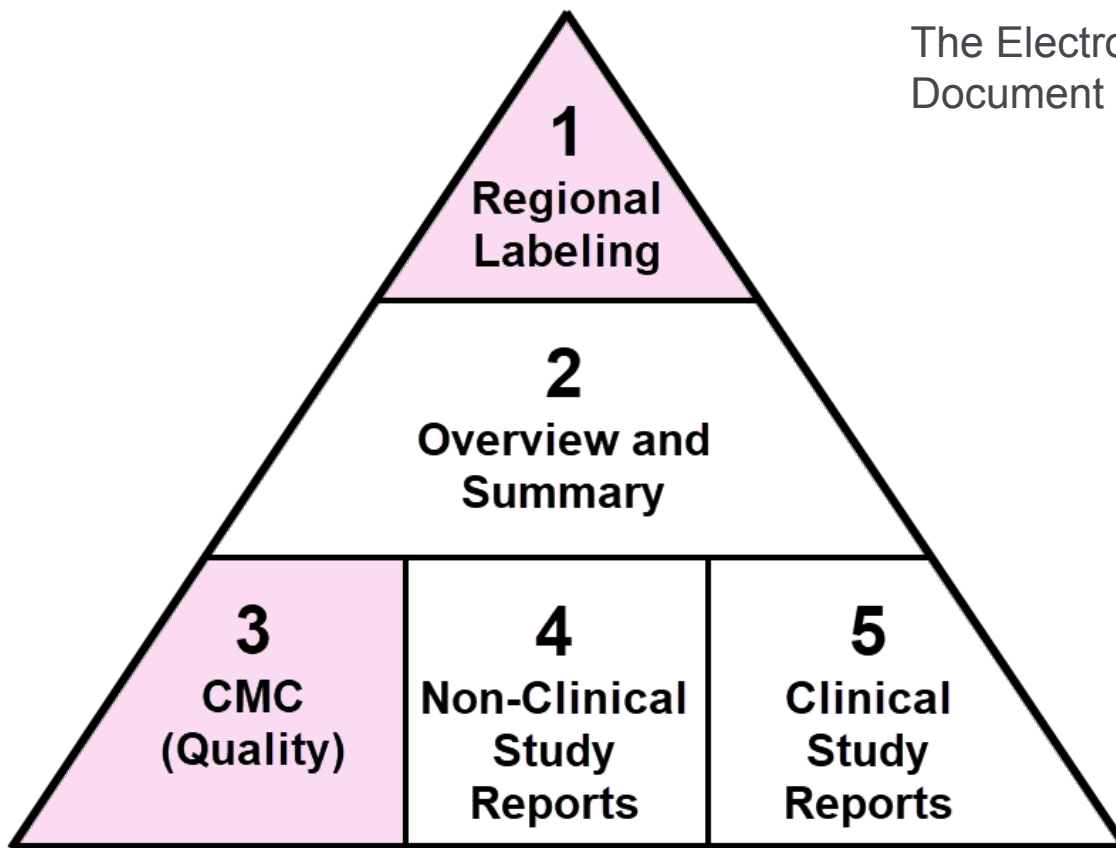


Adapted from <https://gilbane.com/2009/11/what-is-smart-content/>

# Intelligent Structured Content Benefits

- **Reuse/Repurpose** : create content once and reuse it in multiple documents and submissions. Reduces duplication and time/cost of content processes (e.g. translation) – ensures **consistency** & efficiency
- 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**/geneology
- Structure & **Standards** : XML supports industry-specific data structures, easing **compliance** with regulatory requirements and information exchange standards - **guarantees longevity of content**

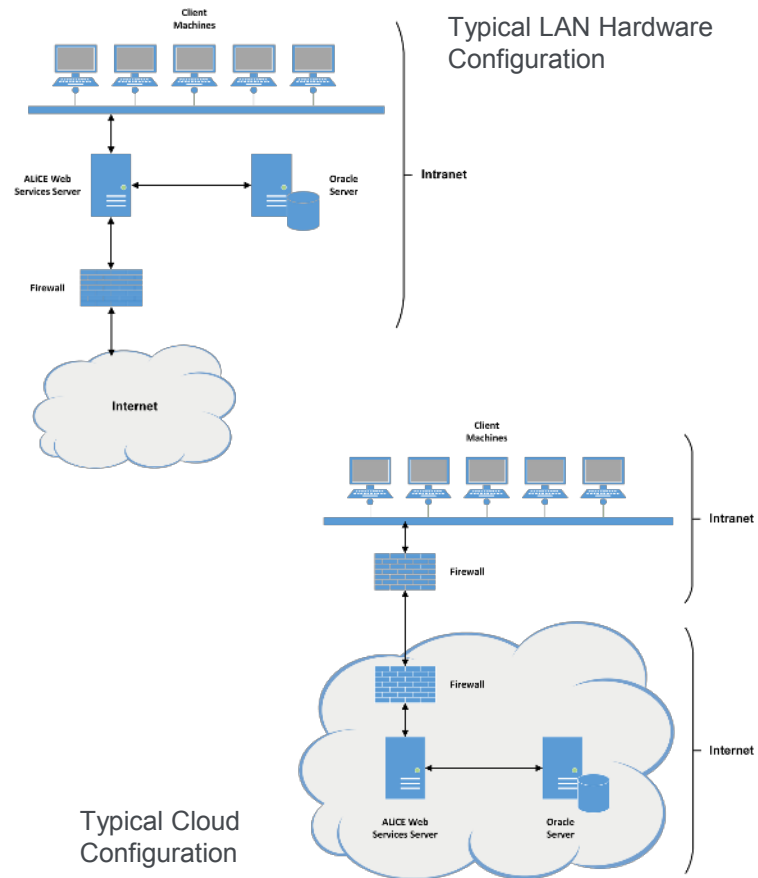
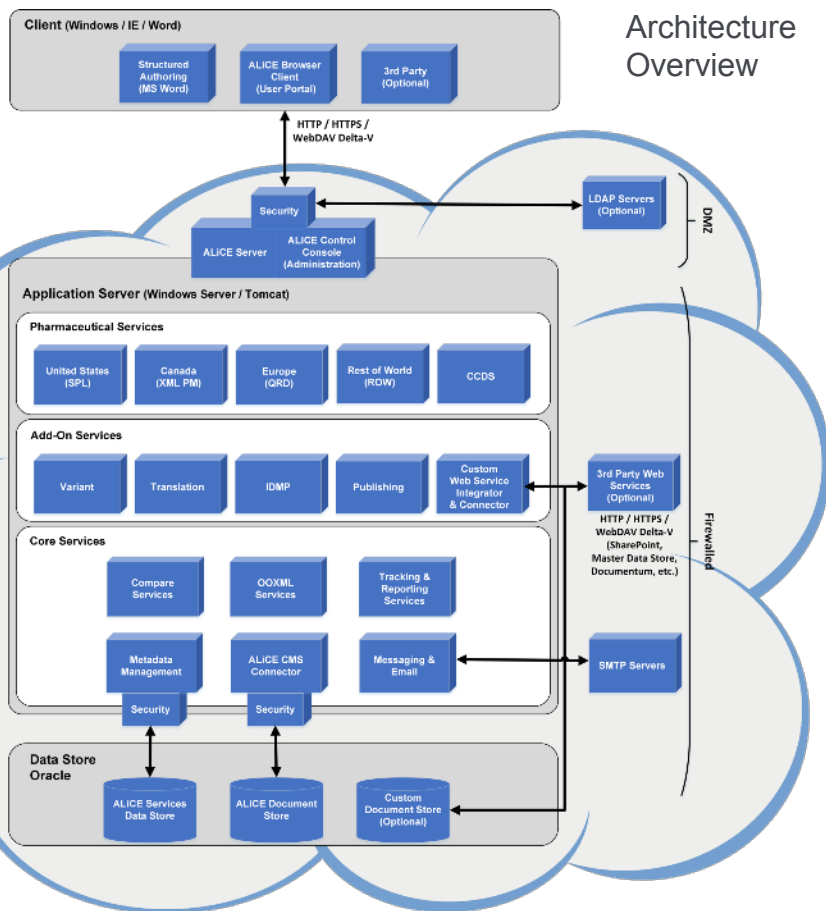
# Globally Align Content



The Electronic Common Technical Document (eCTD) Triangle

Areas where documentation is moving toward using structure are marked in pink.

# A4L Enterprise Architecture



# Structured Content Authoring

Rich Addressable Content

# Structured Templates



2.3.P.QOS: Drug Product

## 2.3.P QUALITY OVERALL SUMMARY - DRUG PRODUCT

### 2.3.P.1 Description and composition of the drug product

<<Click here to enter Description and Composition of the Drug Product>>

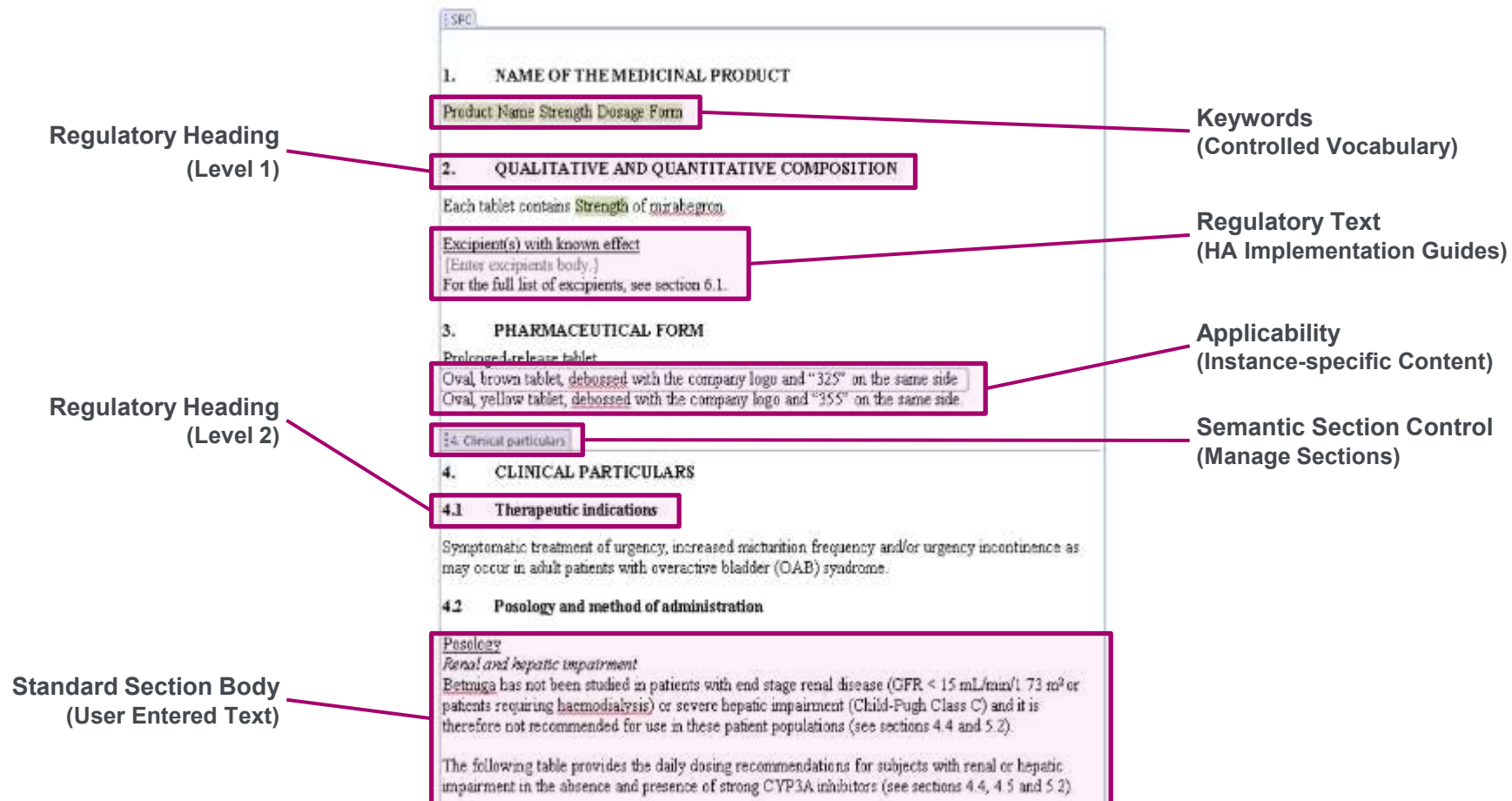
2.3.P.2 Pharmaceutical Development Title

### 2.3.P.2 Pharmaceutical development

<<Click here to enter Pharmaceutical Development>>

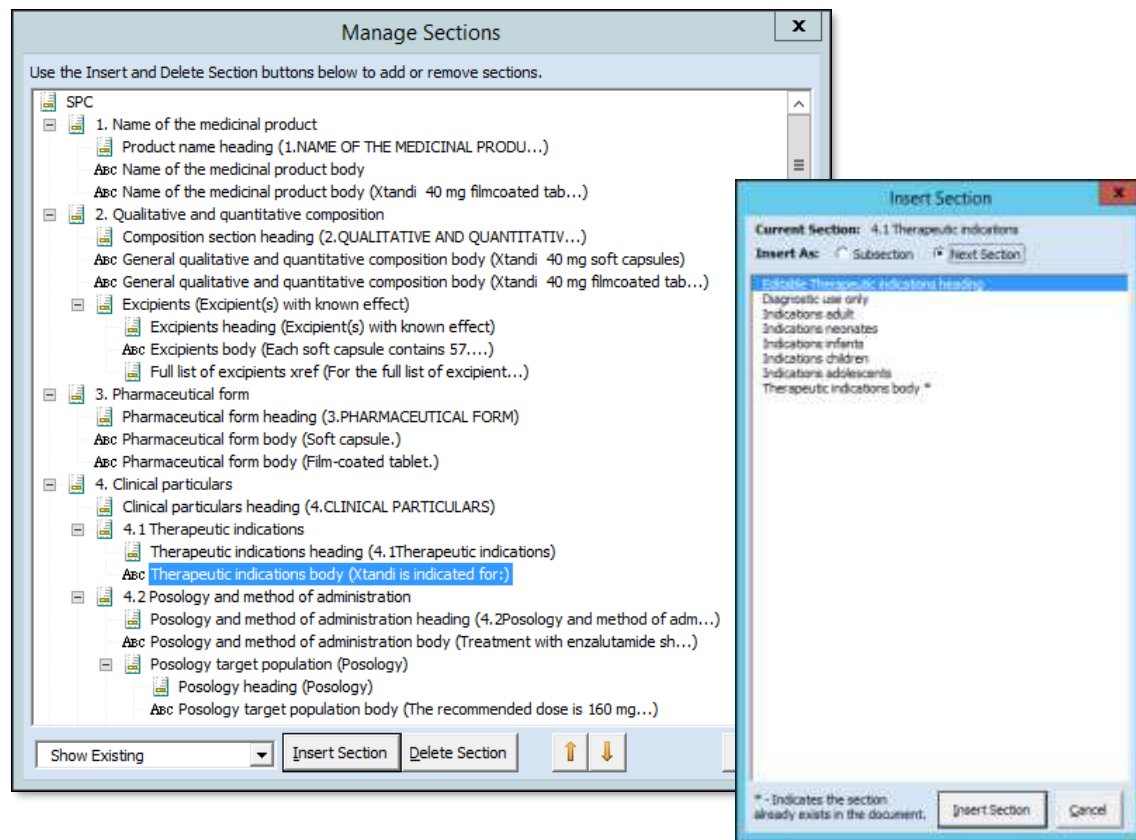
- Microsoft Word Plugin
- Semantically Rich XML Documents
- HA Regulatory Compliance

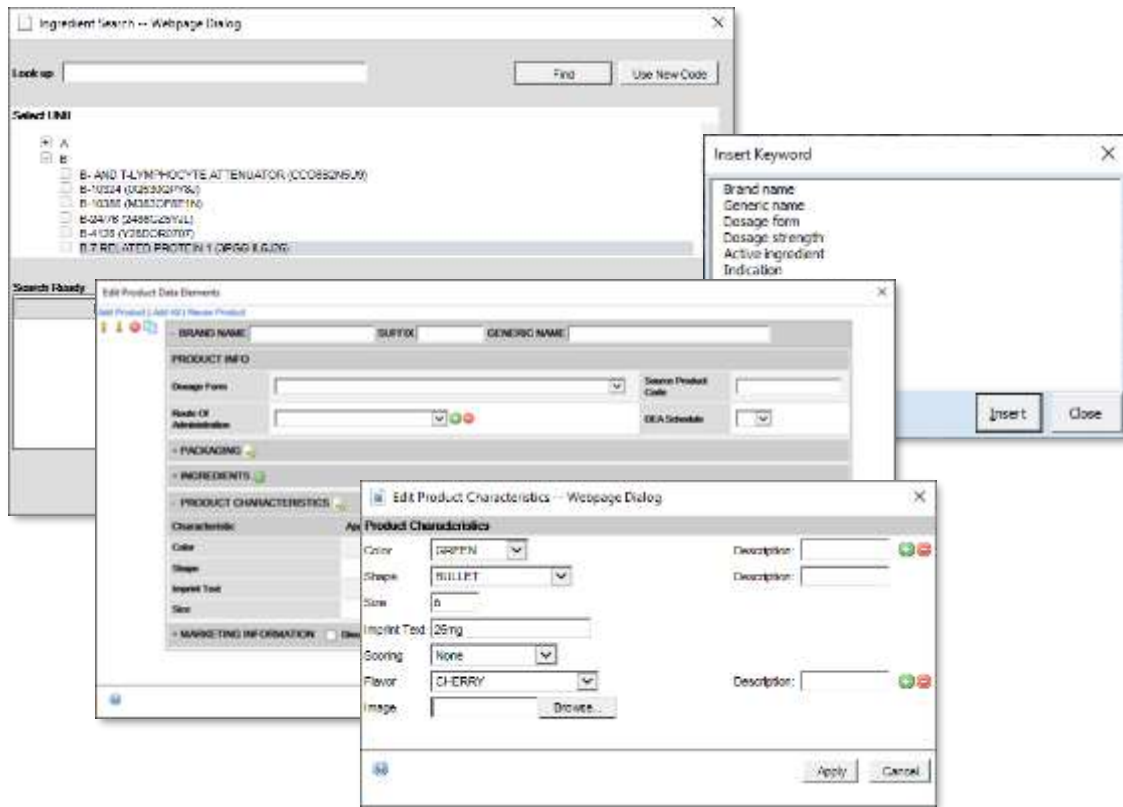
# Applying Structure to Documents



# Manage Semantic Sections

- Manage document structure
- Template enforces structure rules:
  - Context-driven
  - Occurrence rules





- Dictionary / Thesaurus
- Keywords / Variables
- Reusable Content:
  - Lists of Countries, Languages, Product Lines
  - Product Composition, Ingredients, Strengths

# Content and Data: IDMP

## Standards/Industry aligned data identification

The screenshot shows the 'IDMP Data' application window. On the left, there is a sidebar with a 'Manage IDMP Data' button and a list of categories: THERAPEUTIC INDICATIONS, CONTRAINDICATIONS, INTERACTION WITH OTHER MEDICINAL PRODUCTS, and UNDESIRABLE EFFECTS. Below this is a 'View IDMP Data' button. The main area displays a form for a product named 'OSIC 0.4, 0.4 mg, modified release capsules, hard'. The form is divided into sections: 1. NAME OF THE MEDICINAL PRODUCT, 2. QUALITATIVE AND QUANTITATIVE COMPOSITION, 3. PHARMACEUTICAL FORM, 4. CLINICAL PARTICULARS, and 5. THERAPEUTIC INDICATIONS. The 'THERAPEUTIC INDICATIONS' section is highlighted with a red box, and a red line connects it to a dropdown menu on the right. The dropdown menu shows two options: 'IDMP ID: 1 Indication: Benign prostatic hyperplasia Intended Effect: Treatment' and 'IDMP ID: 1 Indication: Lower urinary tract symptoms Intended Effect: Treatment'.

**IDMP Data**

Manage IDMP Data

THERAPEUTIC INDICATIONS  
CONTRAINDICATIONS  
INTERACTION WITH OTHER MEDICINAL PRODUCTS  
UNDESIRABLE EFFECTS

View IDMP Data

**OSIC-Preinset**

1. NAME OF THE MEDICINAL PRODUCT  
OSIC 0.4, 0.4 mg, modified release capsules, hard

2. QUALITATIVE AND QUANTITATIVE COMPOSITION  
Each capsule contains as active ingredient hydrochloride 0.4 mg.  
Excipient(s):  
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM  
Modified release capsule, hard  
34. Clinical particulars (see 0.4 and 701)

4. CLINICAL PARTICULARS

4.1 Therapeutic indications  
Lower urinary tract symptoms (LUTS) associated with benign prostatic hyperplasia (BPH).

4.2 Posology and method of administration  
Oral use  
One capsule daily, to be taken after breakfast or the first meal of the day.  
The capsule must be swallowed whole and must not be crushed or chewed, as this interferes with the modified release of the active ingredient.  
No dose adjustment is warranted in renal impairment. No dose adjustment is warranted in patients with mild to moderate hepatic insufficiency (see also 4.3 Contraindications).

IDMP ID: 1  
Indication: Benign prostatic hyperplasia  
Intended Effect: Treatment

IDMP ID: 1  
Indication: Lower urinary tract symptoms  
Intended Effect: Treatment

The screenshot shows a dropdown menu for the 'Indication' field. The menu is open, displaying a list of medical conditions: Benign prostatic hyperplasia, Benign prostatic hypertrophy, Benign prostatic neoplasm NOS, and NOS. The 'Indication' field is currently set to 'Benign pm'. Below the dropdown menu are three buttons: 'Save', 'Clear', and 'Cancel'.

Indication: Benign pm

Intended Effect: TREA

Race: Benign prostatic hyperplasia

Gender: Benign prostatic hypertrophy

Age Qualifier: Benign prostatic neoplasm NOS

Adjunct Treatment Type: [Dropdown]

Adjunct Treatment: [Dropdown]

Disease Status: [Dropdown]

Co-morbidity: [Dropdown]

Health Status Type: [Dropdown]

Health Status Specifics: [Dropdown]

Duration Qualifier: [Dropdown]

Therapy Relationship Type: [Dropdown]

Save Clear Cancel

# Content and Data: IDMP

## IDMP function/process management Dashboard

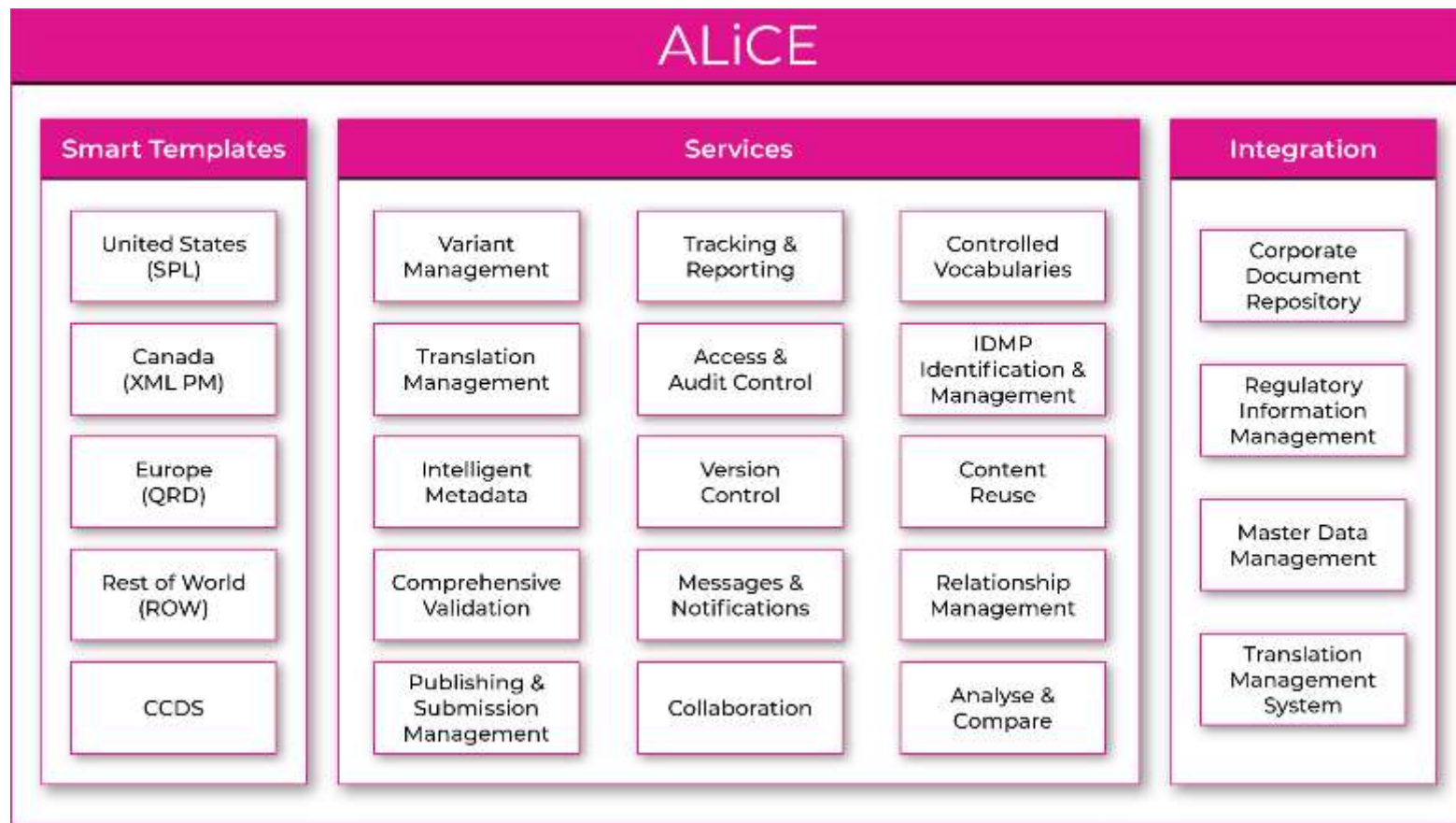
The screenshot shows a web application interface for IDMP management. At the top right, there are several icons: a refresh icon, a save icon, a print icon, a trash icon, a help icon, and a close icon. Below these is a tab bar with a single active tab labeled 'IDMP' and a '+' icon to add more tabs. Under the tab bar is a toolbar with buttons for 'Edit IDMP', 'Check-in', 'Cancel', 'Promote', 'Open', 'History', and a 'Package Operations' dropdown menu. To the right of the toolbar is a button labeled 'Back to Global Labeling Dashboard'. Below the toolbar is a table with the following columns: State, Title, IDMP, IDMP State, IDMP Last Modified, Current User, Label, Label Status, and ID. The table contains one row of data. At the bottom of the interface is a pagination bar showing 'Page 1 of 1' and a dropdown menu set to '5000'. The text 'View 1 - 1 of 1' is displayed on the right side of the pagination bar.

State	Title	IDMP	IDMP State	IDMP Last Modified	Current User	Label	Label Status	ID
	NuDrug SPC-Prescriber en	0.1	Not Tagged	2019-04-30 10:06:01		0.3	Draft	54872

# Structured Content Management

## Global Content Alignment

# Structured Content Management



# Security

## 3 Levels

- Communications via HTTP(S) and servlet restrictions
- User Authentication and logging (passwords)
- Access Control Rights (permission levels)



ALiCE Web Client Login

Enter your ALiCE username and password to continue:

Username:

Password:

Server:  (port: 8080)



Tools SPL Global Labeling Help

Relate As >

 Search... >

---

Signature Report

Update Signature

Export Signature

# Rich Metadata

- Metadata Extraction / Integration
  - Used across RIM ecosystem
- Organize Documents by Metadata
- Metadata Search
- Version Control / Workflow Management

The screenshot shows a software interface with two tabs: 'Drug Overview' and 'File Information'. The 'Drug Overview' tab is active, displaying a list of metadata fields and their values. The 'File Information' tab is also visible, showing fields like Region, Country Group, and Created On.

Drug Overview	
Document Type	Controlled Prescriber and Patient Information
Product Line	
Effective Date	
Registration ID	
Track/Use Number	
Strength (For Title)	25 mg
Product Name	Fulfilat Quadrivalent
INN	Influenza Vaccine (Live Attenuated)
Invented name	
Dosage Form	Spray
Procedure Type	NAP
Initial Year of Approval	
Marketing Start Date	20170825
Marketing End Date	

File Information	
Region	Americas
Country Group	North America
Confidentiality Status	
Created On	2019-05-01 15:49:27
Version Created On	2019-05-01 15:58:38
Version Created By	system
Master Class	GPL
Document Class	Version PL 04

The screenshot shows the 'Search ALICE' interface, which is a search query builder. It features a table with columns for logical operators (AND, OR, XOR), search criteria (Brand Name, Product Characteristics, Color Information, Shape Information, Shape), and values (MP, NP, green, bullet). The interface also includes a 'Search' button, a 'Clear' button, and checkboxes for 'Include Versions' and 'Show All Properties'.

Operator	Criteria	Value
AND	Brand Name	Fulfilat Quadrivalent
AND	Product Characteristics	MP
	Color Information	NP
	Color	green
	Shape Information	NP
	Shape	bullet
AND		
AND		
AND		
AND		

**Search** **Clear** ☐ Include Versions ☐ Show All Properties

**Search Results**

# Content Reuse

## Reusable Components

- Content/Data Reuse  
(*across document types*)

## Applicability

- Master Document
- Content/Data Reuse  
(*in same document type*)

Instance  
Text

Business  
Template

Master  
Text

### 50mg Powder Product

#### 1. NAME OF THE MEDICINAL PRODUCT

Antibiotix 50 mg powder for solution for infusion

#### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains 50 mg Antibiotix

After reconstitution each ml contains 10 mg Antibiotix.

For the full list of excipients, see section 6.1.

#### 3. PHARMACEUTICAL FORM

Powder for solution for infusion.  
White compact powder.

#### 4. CLINICAL PARTICULARS

##### 4.1 Therapeutic indications

Antibiotix is indicated for:

Adults, adolescents ≥ 16 years of age and elderly:

- Treatment of invasive candidiasis.
- Treatment of oesophageal candidiasis in patients for whom intravenous
- Prophylaxis of Candida infection in patients undergoing allogeneic haer transplantation or patients who are expected to have neutropenia (absolu count < 500 cells / µl) for 10 or more days.

### 100mg Powder Product

#### 1. NAME OF THE MEDICINAL PRODUCT

Antibiotix 100 mg powder for solution for infusion

#### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains 100 mg Antibiotix

After reconstitution each ml contains 20 mg Antibiotix.

For the full list of excipients, see section 6.1.

#### 3. PHARMACEUTICAL FORM

Powder for solution for infusion.  
White compact powder.

#### 4. CLINICAL PARTICULARS

##### 4.1 Therapeutic indications

Antibiotix is indicated for:

Adults, adolescents ≥ 16 years of age and elderly:

- Treatment of invasive candidiasis.
- Treatment of oesophageal candidiasis in patients for whom intravenous
- Prophylaxis of Candida infection in patients undergoing allogeneic haer transplantation or patients who are expected to have neutropenia (absolu count < 500 cells / µl) for 10 or more days.

# Translation Management

- Complex process
- Automated translation of standard headings/text
- Export / Import (e.g. to translation partners)
- Update



[illegible]

- Dashboard
- Relate Content Across Jurisdictions
- Relate Tagged Information Across Jurisdictions

# Content Semantic Analytics

Antibiotix Adverse Report Run: 21-08-23, 16:17:15

Data Element (Term) Occurrence per Document Class

Total Documents: 6 Total Terms: 9	CCDS Documents: 1 In   Not In		PI R4 Documents: 1 In   Not In		SPC Documents: 4 In   Not In	
Abortions	1	0	1	0	4	0
Anthrax	1	0	1	0	4	0
Dialysis	0	1	0	1	4	0
Hepatic failure	0	1	1	0	4	0
Infection	1	0	1	0	4	0
Prostatitis	0	1	0	1	4	0
Renal failure	1	0	0	1	3	1
Stomach	0	1	0	1	4	0
Urinary tract infection	1	0	1	1	0	4

Report copyright © 2021 i4i Inc. All rights reserved. Report content is copyright of their respective owners.

Sections identified by semantic meaning in structured documents allow a machine-process to semantically analyse content to:

- Identify concepts within sections
- Attempt to match these concepts appropriately across:
  - Document Types
  - Jurisdictions
  - Products

# Variant Management

- Need for concurrent parallel authoring and submissions
- Dashboard in our ALiCE solution

Replace Version		Merge Action		Package
	Vers			
CAP PLR4	0.2			
CAP PLR4	0.2			
94386 -	0.2	0.1	2019-02-15 12:34:44	

<p>2 DOSAGE AND ADMINISTRATION</p> <p>2.1 Dosage and Administration Summary</p> <p>The recommended dose of <b>0.160 mg</b> <b>granules</b> (four 40 mg capsules) administered orally once daily. <b>0.160 mg</b> can be taken with or without food [see <b>Clinical Pharmacology</b> (12.3)]. Swallow capsules whole. Do not chew, dissolve, or open the capsules [see <b>How Supplied Storage, Packaging, and Handling</b> (16)].</p> <p>Caffeine Citrate Injection USP for <b>concentrate, concentrate, injection</b> is clear, colorless, sterile, non-pyrogenic, preservative-free, aqueous solutions adjusted to pH 4.3.</p> <p>This is the <b>replaced</b> numbered list:</p> <ol style="list-style-type: none"> <li>Grade 3 toxicity or an intolerable side effect, withhold dosing for one week or until symptoms improve to <math>\leq</math> Grade 2, then resume at the same or a reduced dose (120 mg or 80 mg), if warranted [see Warnings and Precautions (5.1) (5.2)].</li> <li>The concomitant use of strong CYP2C8 inhibitors should be avoided if possible. If patients must be co-administered a strong CYP2C8 inhibitor, reduce the <b>0.160 mg</b> dose to 80 mg once daily.</li> <li>If co-administration of the strong inhibitor is <b>replaced</b>, the <b>0.160 mg</b> dose should be returned to the dose used prior to initiation of the strong CYP2C8 inhibitor [see Drug Interactions (7.1) and Clinical Pharmacology (12.3)].</li> <li>The concomitant use of strong CYP3A4 inducers should be avoided if possible. If patients must be co-administered a strong CYP3A4 inducer, increase the <b>0.160 mg</b> dose from 160 mg to 240 mg once daily.</li> <li>If co-administration of the strong CYP3A4 inducer is discontinued <b>and replaced</b>, the <b>0.160 mg</b> dose should be returned to the dose used prior to initiation of the strong CYP3A4 inducer [see Drug Interactions (7.2) and Clinical Pharmacology (12.3)].</li> </ol> <p>3 DOSAGE FORMS AND STRENGTHS</p> <p><b>Highlight:</b></p> <p>Capsule 40 mg</p> <p>40 mg Capsules are white to off-white, oblong soft gelatin capsules imprinted in black ink with <b>0.160</b>.</p> <p><b>Table 1. Edited Table Caption</b></p> <table> <tr> <th>Column 1</th><th>Replaced Column 2</th><th>Added Extra Column 3</th></tr> <tr> <td>Tests Tests Tests</td><td>Test</td><td>Test</td></tr> </table> <p>The source of this table is the <b>old website</b>.</p> <p>4 CONTRAINDICATIONS</p> <p><b>0.160 mg</b> is contraindicated in women who are or may become pregnant. <b>0.160 mg</b> can cause fetal harm and potential loss of pregnancy [see Use in Specific Populations (8.1)].</p>	Column 1	Replaced Column 2	Added Extra Column 3	Tests Tests Tests	Test	Test	<p>Angelo Evangel... Deleted: <b>granules</b></p> <p>ALICE Phage... Deleted: <b>0.160</b></p> <p>Angelo Evangel... Deleted: <b>Four capsules</b></p> <p>Angelo Evangel... Deleted: <b>capsules</b></p> <p>ALICE Phage... Deleted: <b>Clinical Pharmacology</b></p> <p>ALICE Phage... Deleted: <b>January 28, 2019</b></p> <p>Deleted: <b>Clinical Pharmacology (12.3)</b></p> <p>Angelo Evangel... Deleted: <b>capsules</b></p> <p>Angelo Evangel... Deleted: <b>Each mL contains 20 mg</b></p> <p>Angelo Evangel... Deleted: <b>from</b></p> <p>Angelo Evangel... Deleted: <b>12 a patient</b></p>	<p>Angelo Evangel... Deleted: <b>concentrate</b></p>
Column 1	Replaced Column 2	Added Extra Column 3						
Tests Tests Tests	Test	Test						
<p>Angelo Evangel... Deleted: <b>white</b></p> <p>Angelo Evangel... Deleted: <b>Extra</b></p> <p>Angelo Evangel... Deleted: <b>1</b></p> <p>Angelo Evangel... Deleted: <b>Extra</b></p> <p>Angelo Evangel... Deleted: <b>Formatted Table</b></p> <p>Angelo Evangel... Deleted: <b>Tests</b></p> <p>ALICE Phage... Deleted: <b>Test</b></p> <p>Angelo Evangel... Deleted: <b>Test</b></p> <p>ALICE Phage... Deleted: <b>old website</b></p>								

# Validation

Structured documents can be read by machines to test the validity of the document's structured sections, content formatting, and included elements.

Additionally, it can ensure that health authority rules are being followed and warn you of violations while you are still authoring or before you file your submission.

**Validation Report - ANTIHOTOX**

Show All Show Passed Show Warnings Show Errors

**VALIDATION SUMMARY**

Total Passed: 60  
Total Warnings: 0  
Total Failed: 0

**Document Structure Tests**

- Highlights test - Passed
- Highlights content - Passed
- Section structure - Passed
- Section body structure - Passed
- Heading markup - Passed
- Heading nesting - Passed
- Unmarked content - Passed
- Content outside of a structured section - Passed
- Delimiters - Passed
- Options - Passed
- Root element tag - Passed
- Table content - Passed

**Custom Formatting Tests**

- Highlighting test - Passed
- Font color test - Passed
- Background test - Passed
- Font size test - Passed
- Shading test - Passed
- Border test - Passed
- Text alignment test - Passed
- Formatted space test - Passed

**Image tests**

- Image alt text test - Passed
- Image alt text test - Passed
- Image alt text test - Passed
- Image alt text test - Passed
- Image alt text test - Passed
- Image alt text test - Passed
- Image alt text test - Passed
- Image alt text test - Passed
- Image alt text test - Passed
- Image alt text test - Passed

**Table tests**

- Table test - Passed

**Schema Parsing (Overall: - PASSED)**

- Schema Parsing - passed
- Release Validation - passed

**Tier 1 Validation (Overall: - PASSED)**

- File Name test - passed
- XML Reference test - passed
- Image test - passed
- Setid test - passed
- Code test - passed
- <id> test - passed
- Title test - passed
- EffectiveTime test - passed

**Overall validation status: PASSED**

**Schema Parsing (Overall: - PASSED)**

- Schema Parsing - passed
- Release Validation - passed

**Tier 1 Validation (Overall: - PASSED)**

- File Name test - passed
- XML Reference test - passed
- Image test - passed
- Setid test - passed
- Code test - passed
- <id> test - passed
- Title test - passed
- EffectiveTime test - passed

**Linking Validation (Overall: - PASSED)**

- Linker info test - passed
- Page number info test - passed
- Encounter info test - passed
- SP, Encounter Data test - passed

**Product Data Elements Validation (Overall: - PASSED)**

- Product Section test - passed
- Product name test - passed
- Form and Route test - passed
- Product Code test - passed
- Product Version consistency Test - passed
- Product Source test - passed
- Ingredient test - passed
- Packaging test - passed
- Part quantity test - passed
- Manufacturing category test - passed
- Manufacturing process test - passed
- DCA test - passed
- Import source test - passed
- Import stage test - passed
- Import batch test - passed
- Import scoring test - passed
- Import import code test - passed
- Import factor test - passed
- Import image test - passed
- SP, Encounters Data test - passed
- Import date test - passed

**Content of Linking Validation (Overall: - PASSED)**

- Section test - passed
- Highlighting test - passed
- SP, Encounters Data test - passed
- Image test - passed

Total Passed: 60  
Total Warnings: 0  
Total Failed: 0

**Document Structure Tests**

- Highlights test - Passed
- Highlight content - Passed
- Section structure - Passed
- Section body structure - Passed
- Heading markup - Passed
- Heading nesting - Passed

**Schema Parsing (Overall: - PASSED)**

- Schema Parsing - passed
- Release Validation - passed

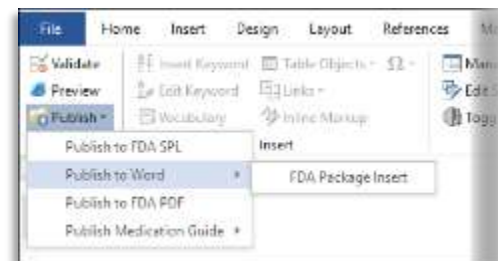
**Tier 1 Validation (Overall: - PASSED)**

- File Name test - passed
- XML Reference test - passed
- Image test - passed
- Setid test - passed
- Code test - passed
- <id> test - passed
- Title test - passed
- EffectiveTime test - passed

# Multi-Platform Publishing

SPL	Global Labeling	Help
New Labeler Code Request New Establishment Registration New Lot Distribution Report		
Edit Labeler and Manufacturer Edit Lot Data Produce New Version		
Import Existing SPL Submission Import Lot Distribution Data Import Product Listing Data		
Validate SPL Preview Submission Manage SPL Submission Date <b>Generate Submission</b> Mark as Accepted		
SPL Usage Report SPL Submission History		

- Health Authority Specific (FDA SPL, EMA EPAR, etc.)
- Various content from the same source (e.g. Package Insert vs. Medication Guide)
- Various formats from the same source:
  - Word, PDF, and XML for Submissions
  - HTML for Web site



Published

Title:EU Publish

Rule:Consolidated QRDS

Format:

☐ docx☐ pdf☒ doc

Condition:

☒ Track Changes☐ Comments☐ IDMP Comments

Identifier	Title	Modified By	Last Modified	Published Ver.	Selected Ver.	Latest Ver.
24546	TAB SPC EMA en 194386	Annie John Sandy	2019-03-11 14:24:55	<input checked="" type="checkbox"/> v1.27 (Internally Approved)	<input type="checkbox"/> v3.0 (Release)	<a href="#">History</a> v1.1 (Review)
24548	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24549	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24550	TW106520	regis@pds Manager	2018-11-16 10:01:50	<input checked="" type="checkbox"/> v1.18 (Internally Approved)	<input type="checkbox"/> v1.23 (Submitted)	<a href="#">History</a> v1.23 (Submitted)
24551	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24552	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24553	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24554	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24555	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24556	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24557	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24558	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24559	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24560	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24561	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24562	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24563	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24564	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24565	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24566	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24567	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24568	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24569	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24570	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24571	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24572	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24573	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24574	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24575	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24576	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24577	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24578	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24579	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24580	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24581	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24582	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24583	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24584	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24585	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24586	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24587	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24588	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24589	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24590	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24591	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24592	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24593	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24594	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24595	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24596	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24597	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24598	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24599	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24600	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24601	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24602	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24603	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24604	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24605	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24606	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24607	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24608	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24609	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24610	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24611	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24612	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24613	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24614	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24615	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24616	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24617	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24618	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24619	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24620	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24621	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)
24622	TW106510	John Kim	2018-11-12 14:07:51	<input type="checkbox"/> v6.2 (Draft)	<input type="checkbox"/> v6.2 (Draft)	<a href="#">History</a> v1.2 (Draft)

Select/Invert All

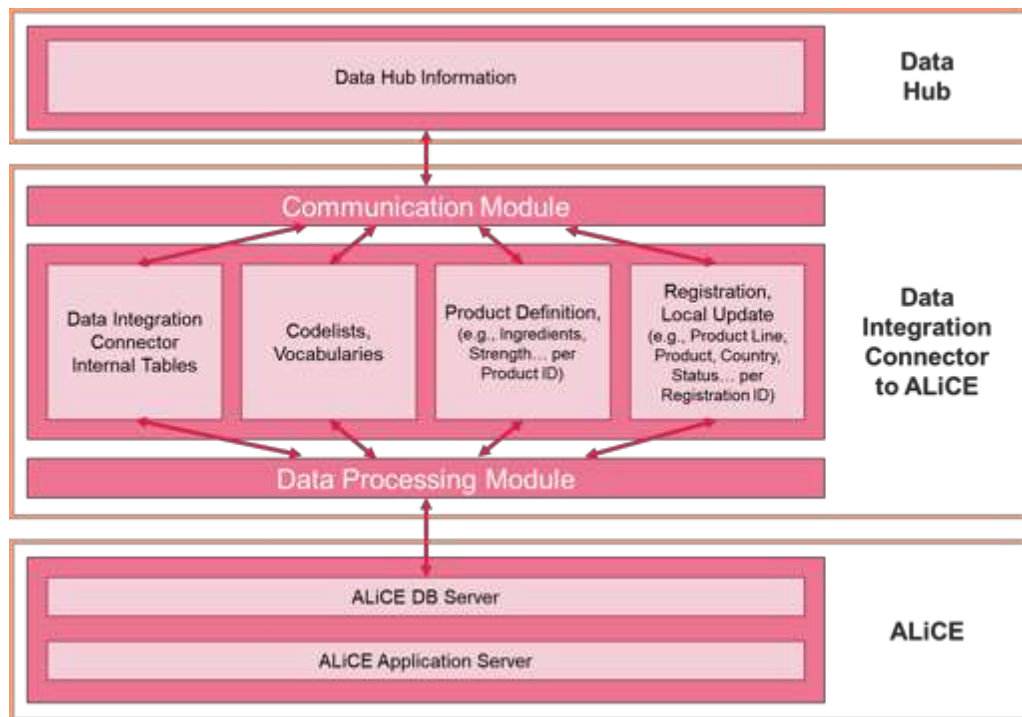
Publishing Structure

Save

Publish

Cancel

# Integration



- Share aligned data with data hubs
  - (e.g. controlled vocabularies, product definitions, jurisdictional registration, IDMP data)
- Enables auto-population and auto-update of information from Data Hub in documents
- Alignment of data through Pre- and Post- processing
- Push/Pull data securely
  - On Schedule/On Demand
- Data Aware – compare product information and informs user of changes/discrepancies

# Global Content Alignment

## Intra-Jurisdictional



- Templates
- Applicability
- Keywords/Variables

## Inter-Jurisdictional




- Compliance view
- Semantic Analytics
- Translation

## Cross Product



- Reusable Components
- Variant management



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



## 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  
E-mail: [info@i4i.com](mailto:info@i4i.com)

<https://www.i4i.com>

Copyright © i4i inc. 1993-2021. All rights reserved.

i4i, x4o, A4L systems logos are trademarks of Infrastructures for Information Inc. and may be registered in certain jurisdictions. All other product names, marks, logos, and symbols may be trademarks of their respective owners