i4i the structured content company

Global Alignment

Managing Compliance Across Jurisdictions from Authoring to Submission

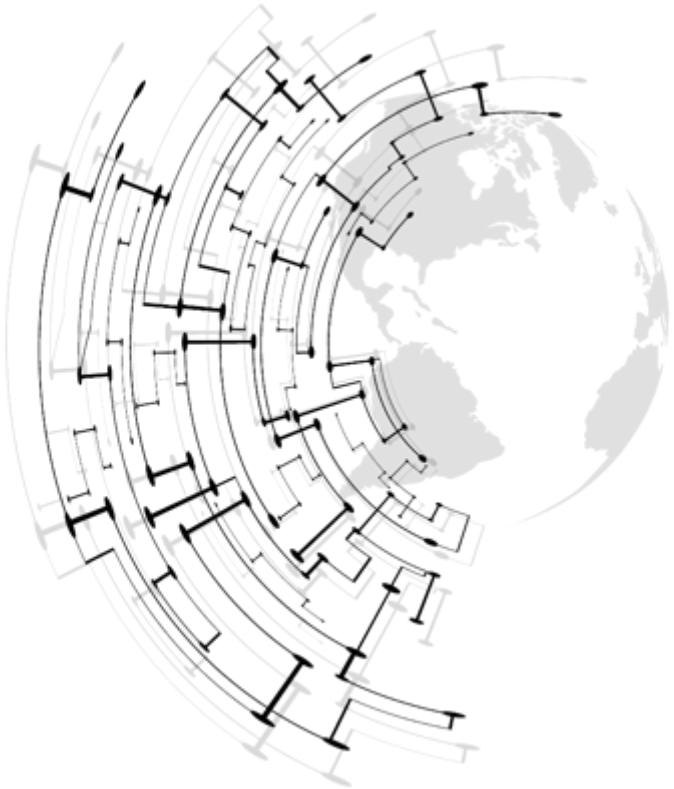
Coffee Corner

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

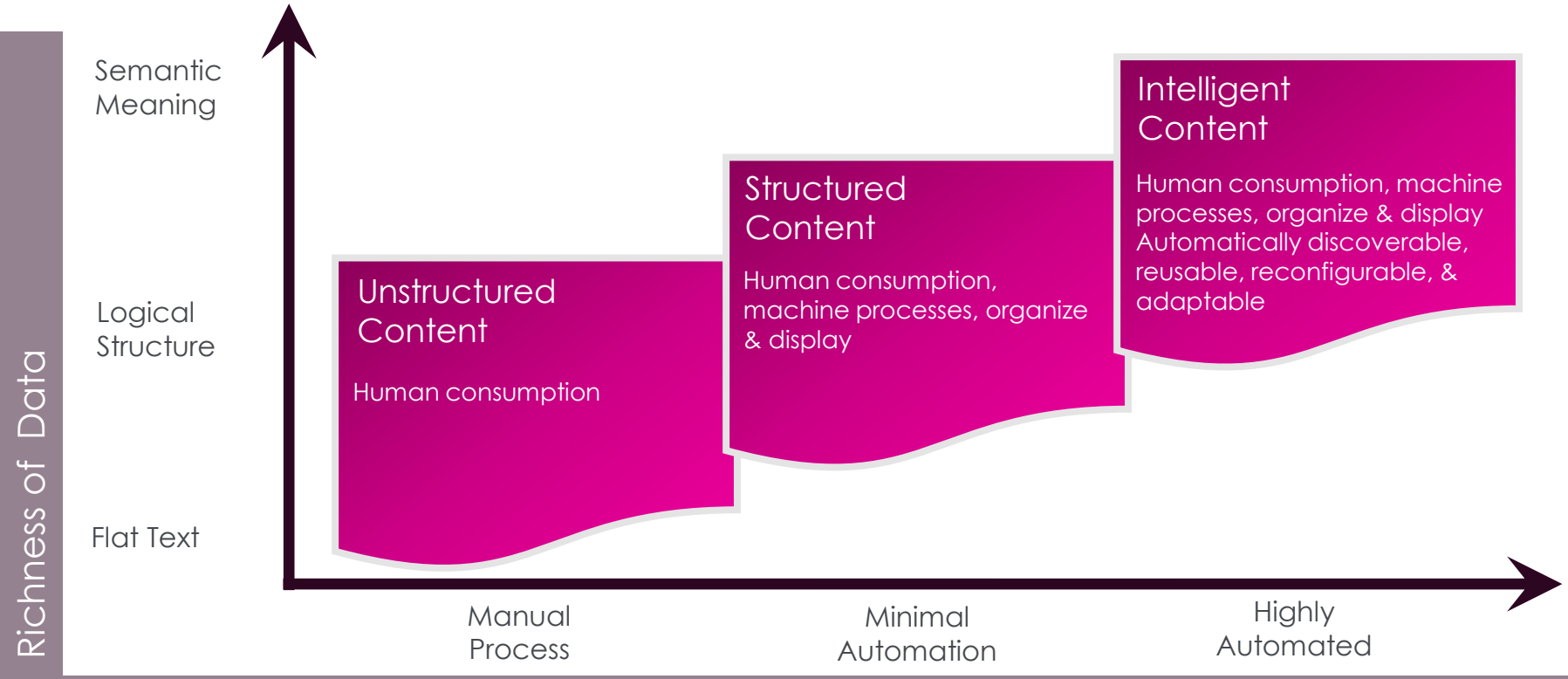
90+

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

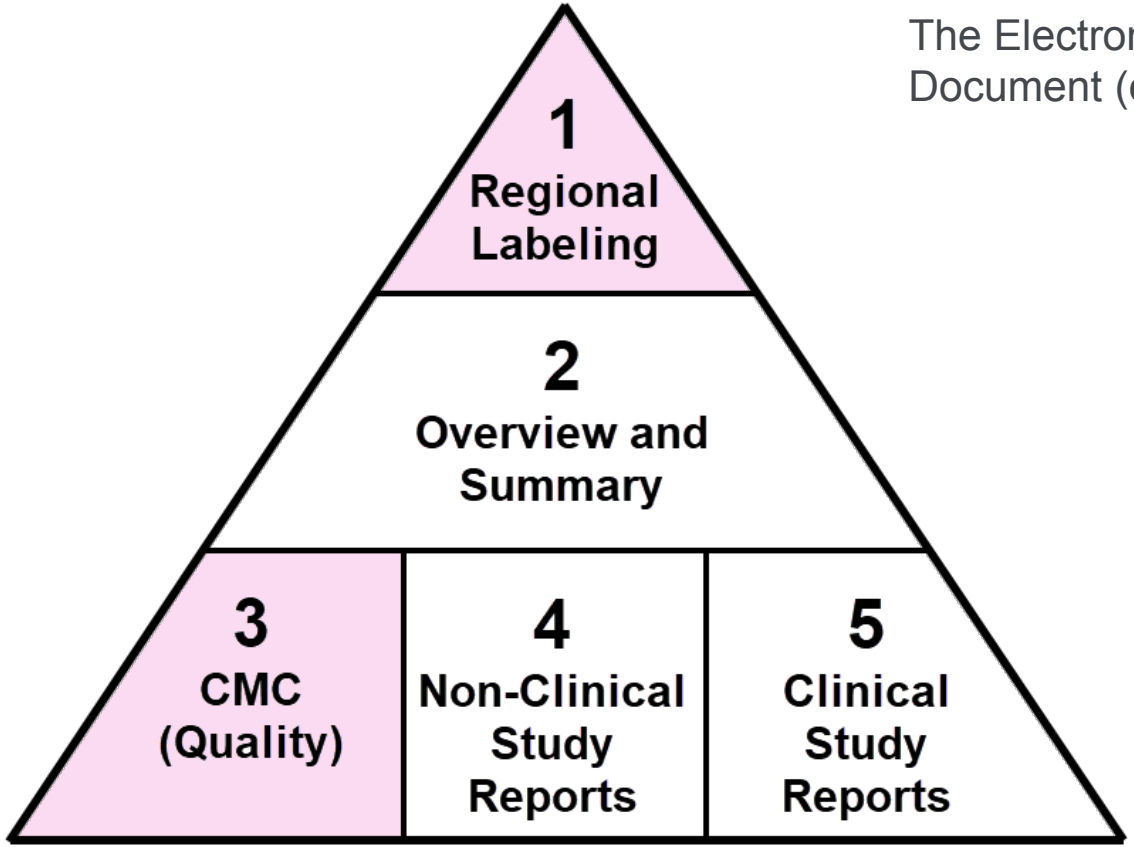


Adapted from https://gilbane.com/2009/11/what-is-smart-content/

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

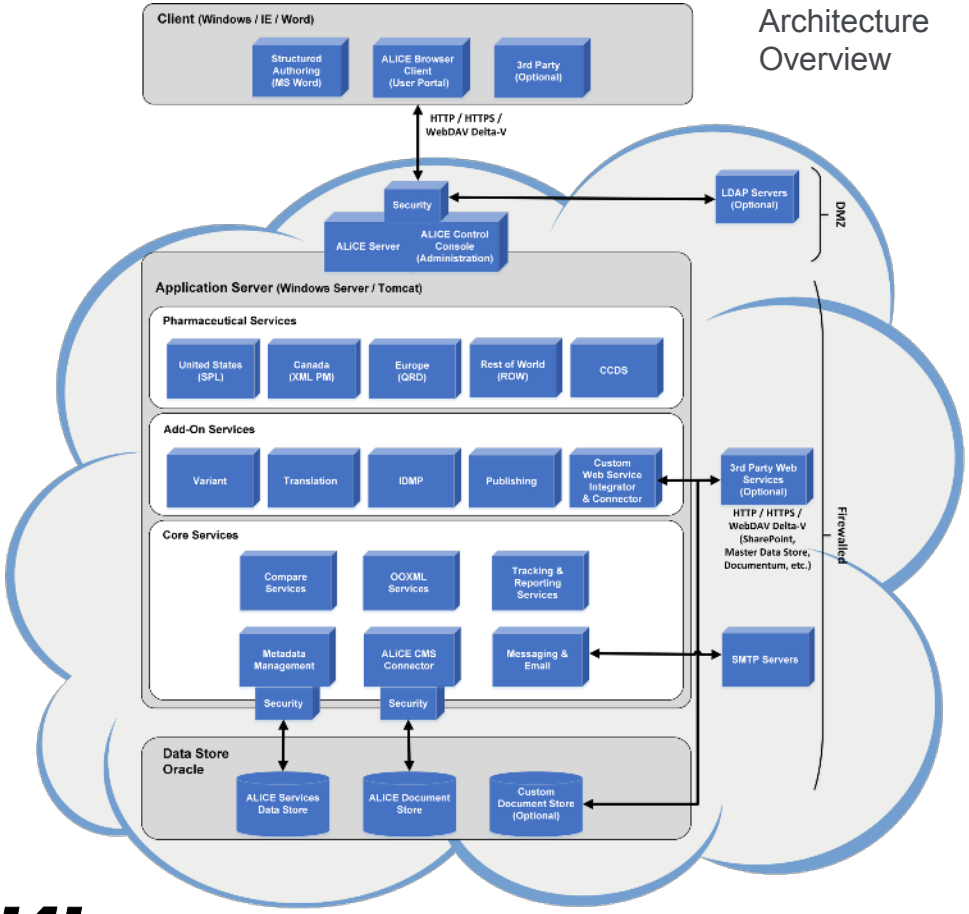


The Electronic Common Technical Document (eCTD) Triangle

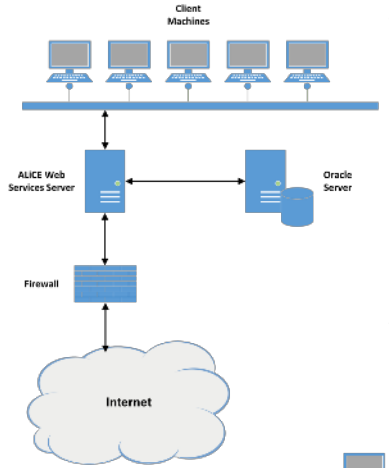
Areas where documentation is moving toward using structure are marked in pink.

A4L Enterprise Architecture

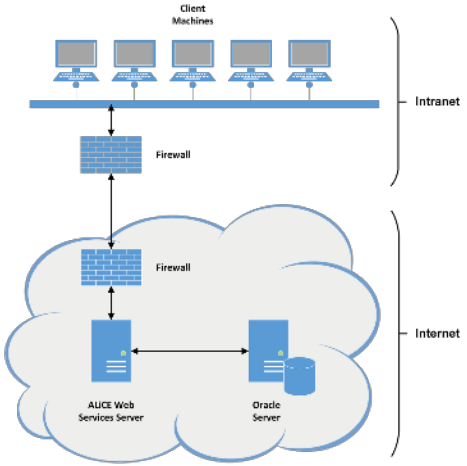
Architecture Overview



Typical LAN Hardware Configuration



Typical Cloud Configuration



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>>

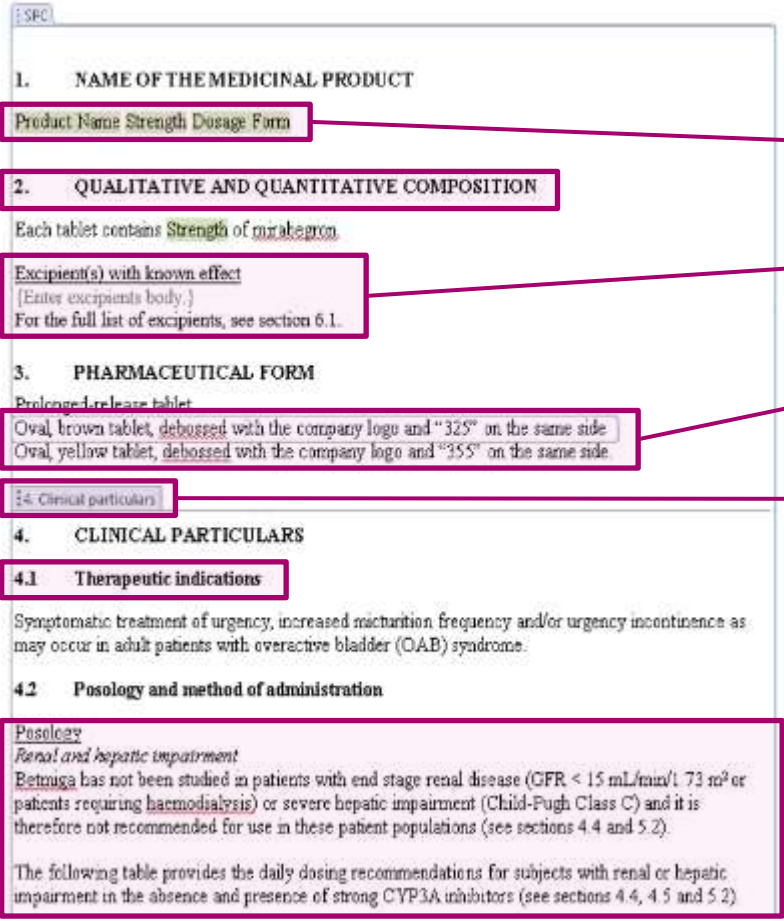
2.3.P.2 Pharmaceutical Development Title

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



Regulatory Heading (Level 1)

Regulatory Heading (Level 2)

Standard Section Body (User Entered Text)

Keywords (Controlled Vocabulary)

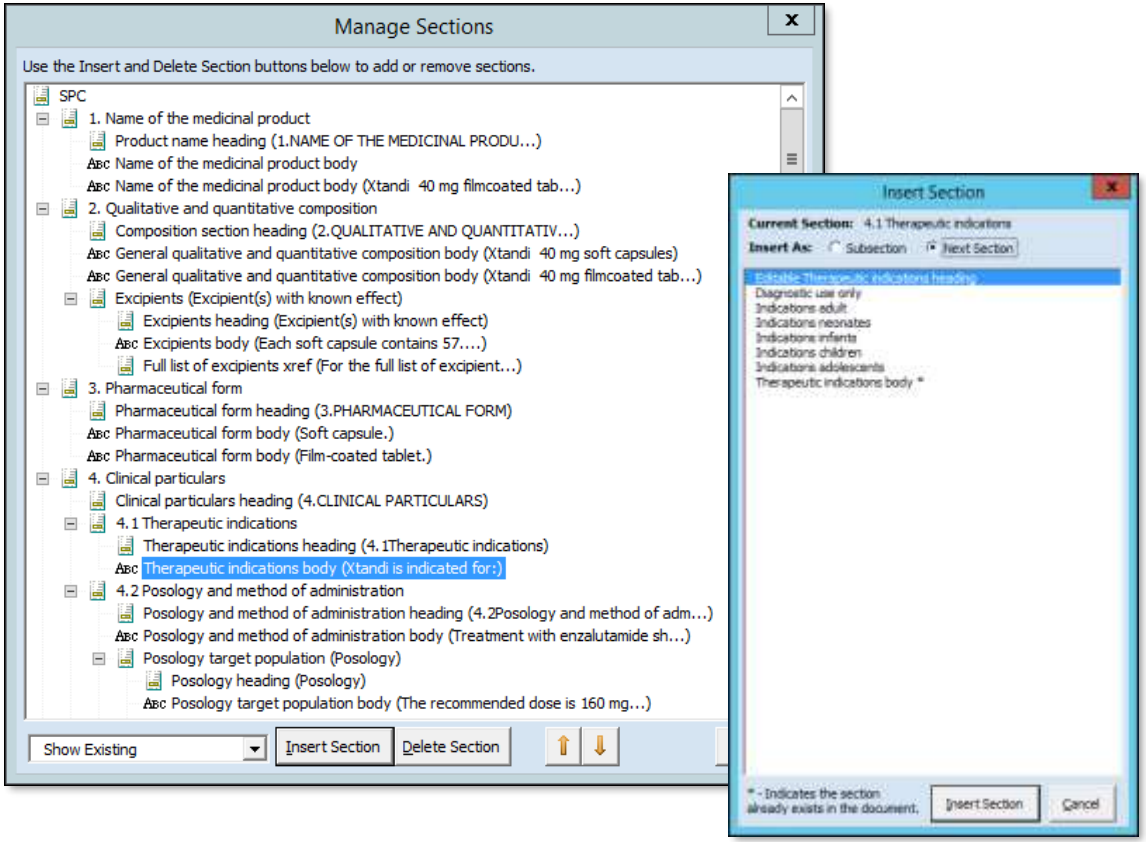
Regulatory Text (HA Implementation Guides)

Applicability (Instance-specific Content)

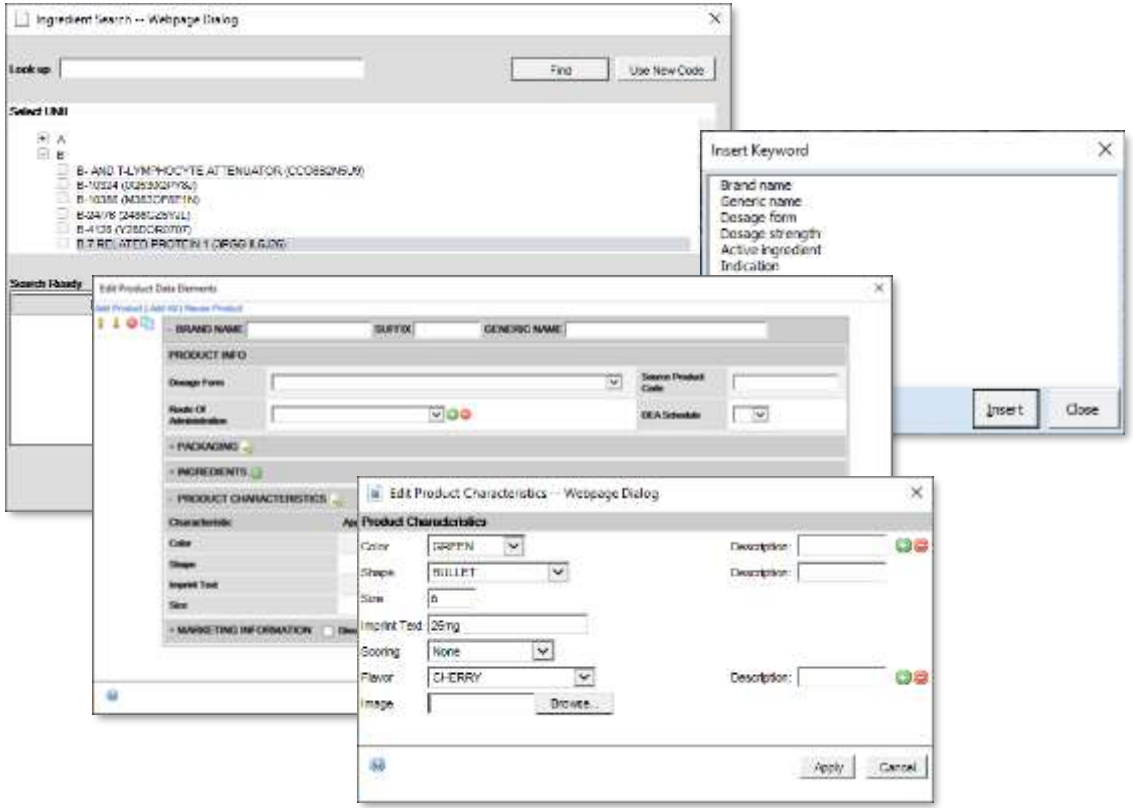
Semantic Section Control (Manage Sections)

Manage Semantic Sections

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



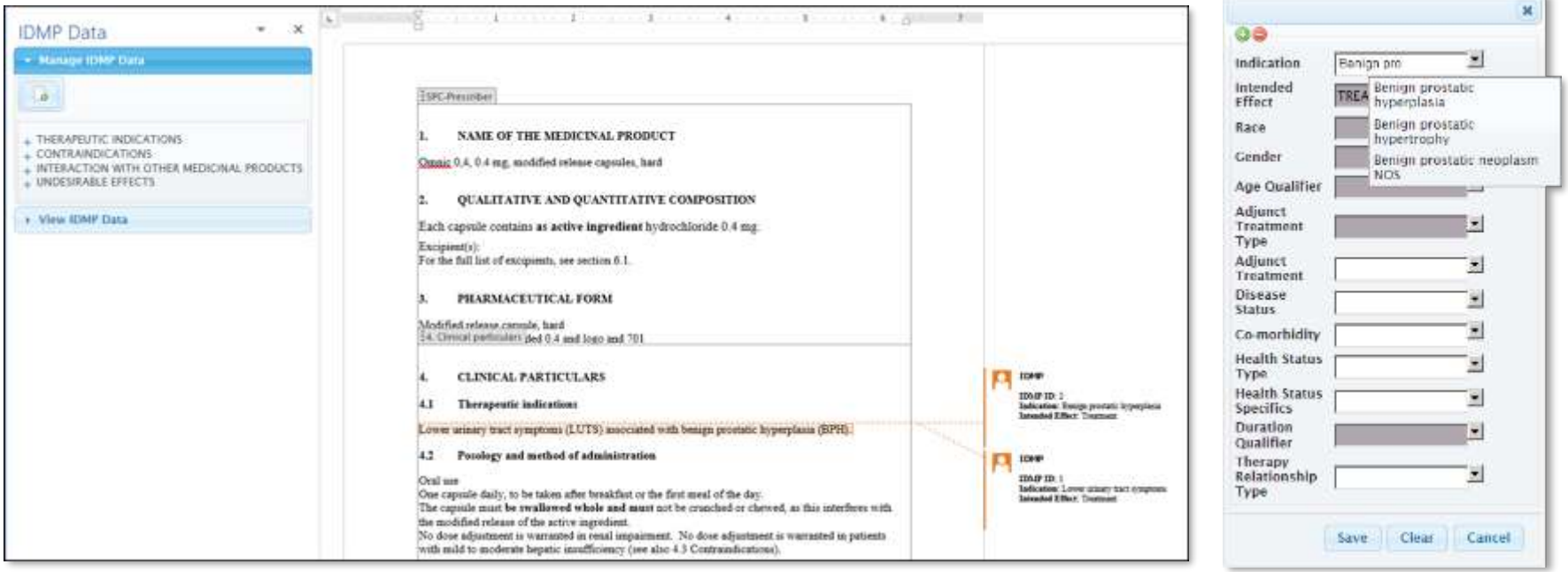
Controlled Vocabulary



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

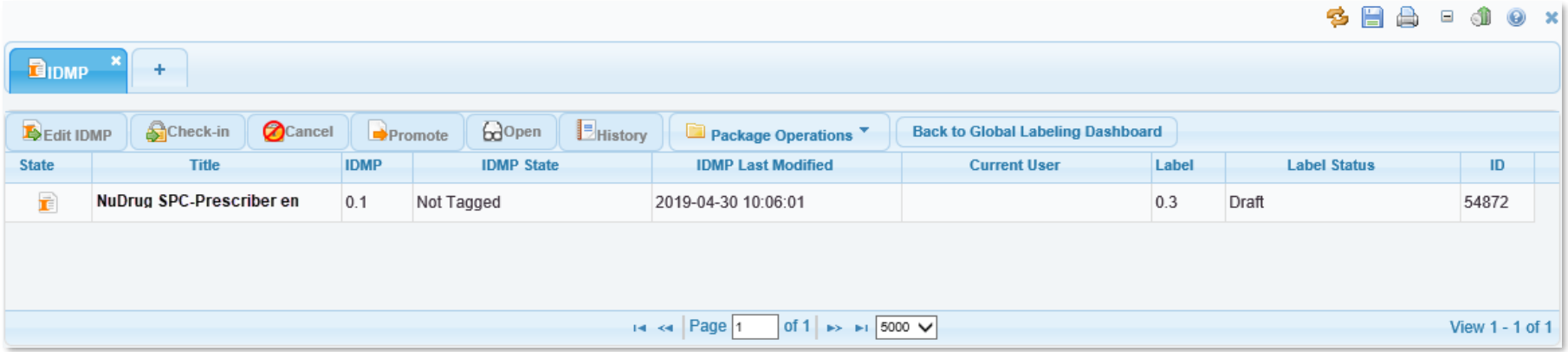
Content and Data: IDMP

Standards/Industry aligned data identification



Content and Data: IDMP

IDMP function/process management Dashboard



Structured Content Management

Global Content Alignment

Structured Content Management

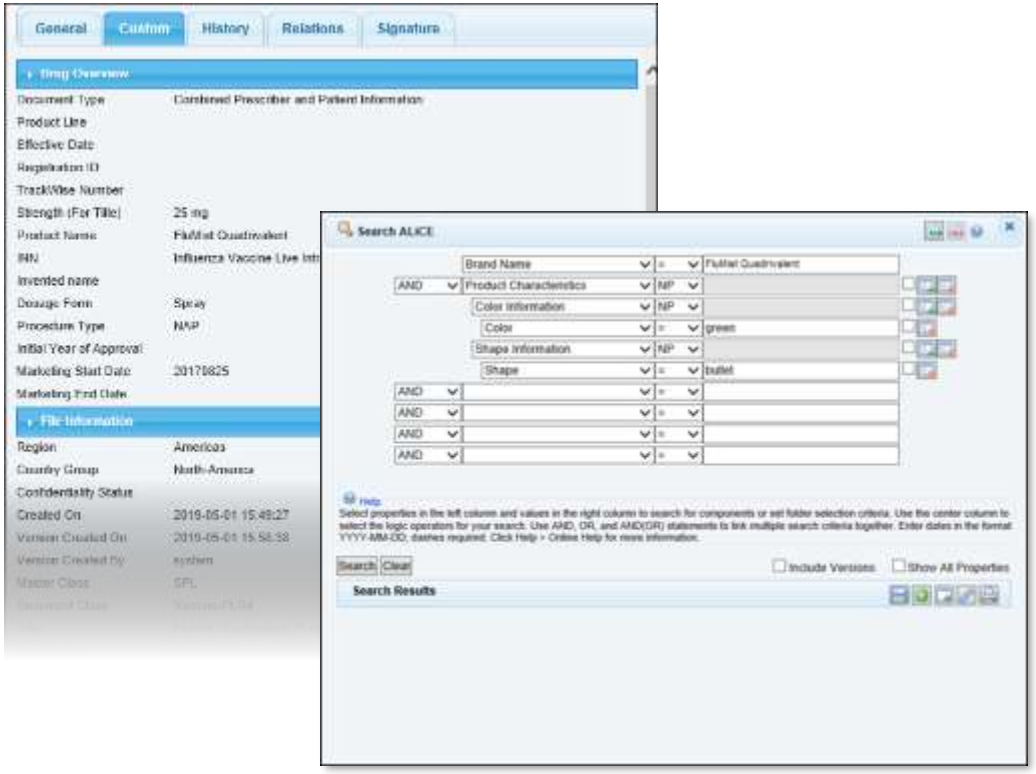
Security

3 Levels

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

Rich Metadata

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



Content Reuse

Reusable Components

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

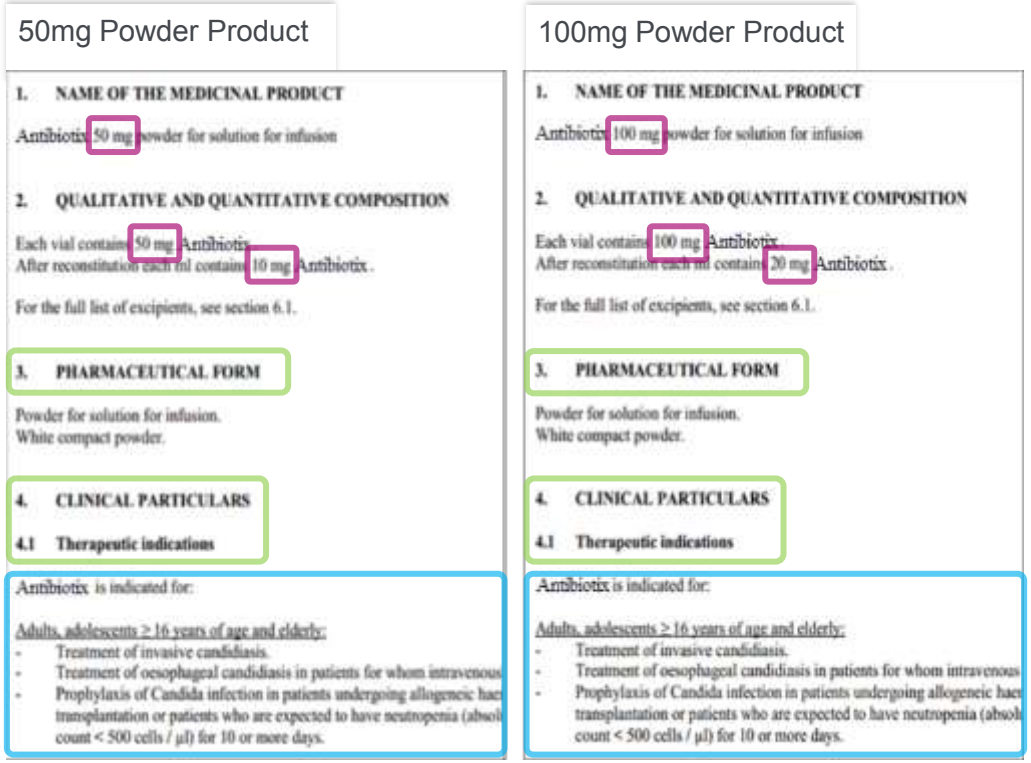
Applicability

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

Instance Text

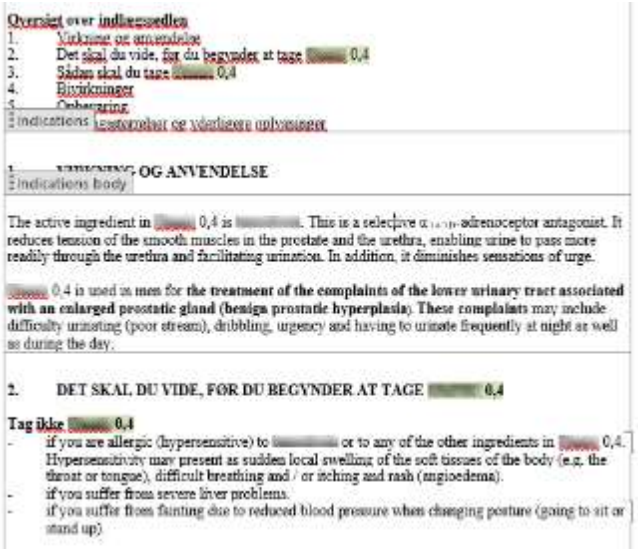
Business Template

Master Text

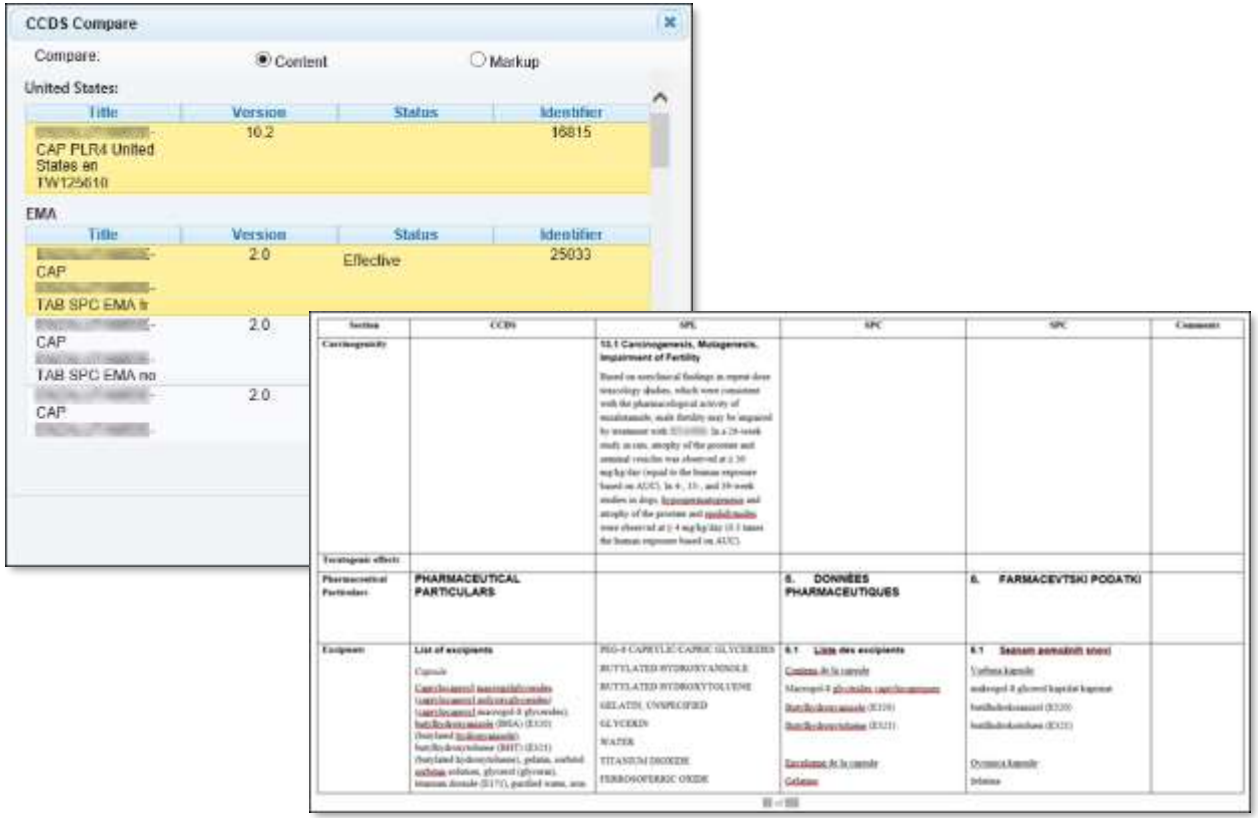


Translation Management

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

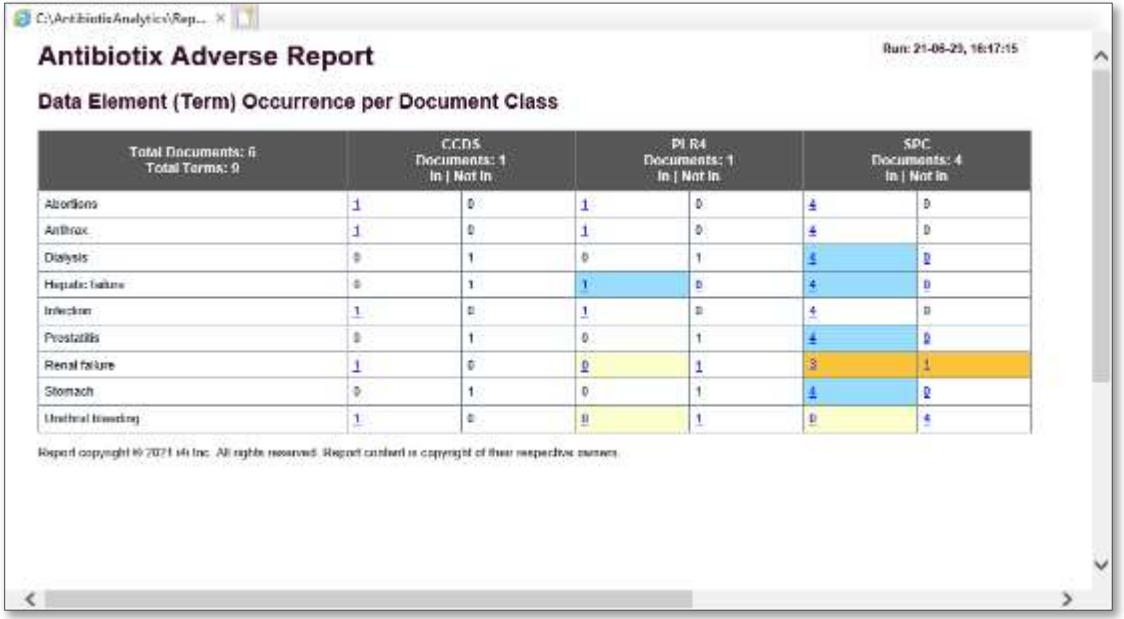


CCDS Compliance



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

Content Semantic Analytics



C:\AntibioticAnalytics\Rep...

Antibiotix Adverse Report

Run: 21-08-29, 16:17:15

Data Element (Term) Occurrence per Document Class

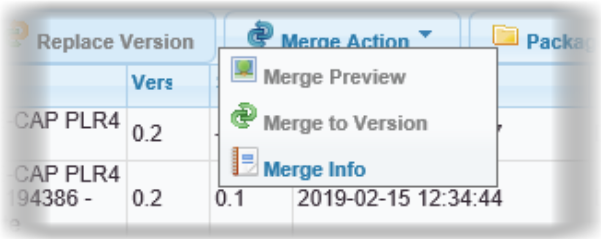
Total Documents: 6 Total Terms: 9	CCDS Documents: 1 In | Not In		PI R4 Documents: 1 In | Not In		SPC Documents: 4 In | Not In	
Abortions	1	0	1	0	4	0
Anthrax	1	0	1	0	4	0
Dialysis	0	1	0	1	4	0
Hepatic failure	0	1	1	0	4	0
Infection	1	0	1	0	4	0
Prostatitis	0	1	0	1	4	0
Renal failure	1	0	0	1	3	1
Stomach	0	1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

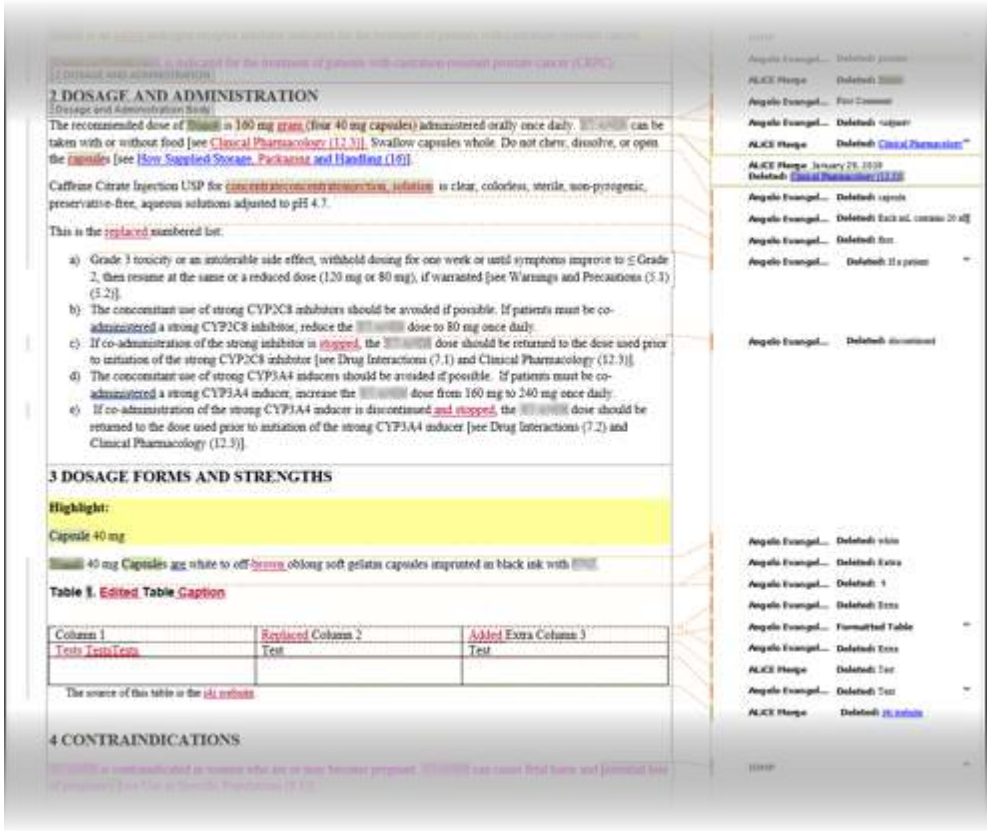
Sections identified by semantic meaning in structured documents allow a machine-process to semantically analyse content to:

- 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





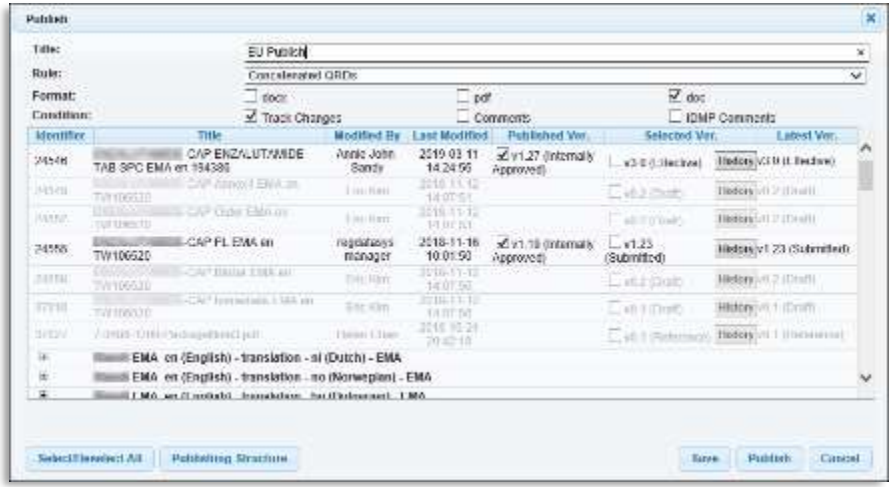
Validation

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

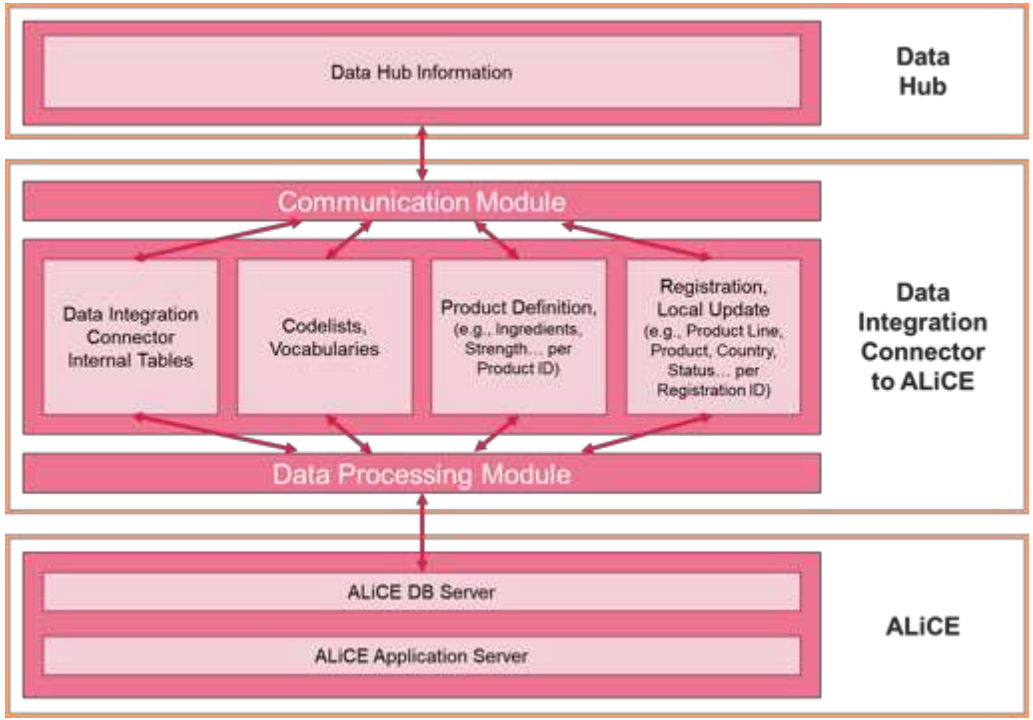
Additionally, it can ensure that health authority rules are being followed and warn you of violations while you are still authoring or before you file your submission.

Multi-Platform Publishing

- 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



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

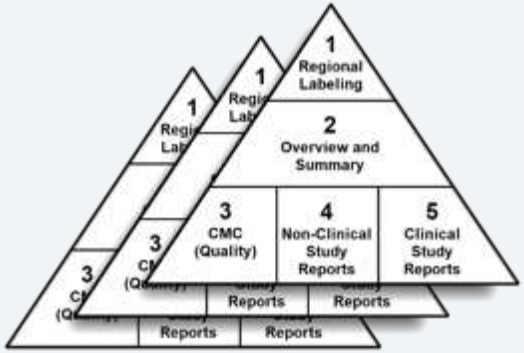
Intra-Jurisdictional

- 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.

i4i the structured content company

Contact i4i

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

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