i4i the structured content company

SPL DIRECT

Compliance & Regulatory Services for Structured Product Labelling & ACA6004

Solving Today's Regulatory Issues

From its inception in 2005, i4i has been on the forefront as a leading contributor to the development of the Structured Product Labeling (SPL) standard. As the guidance continues to evolve and expand to include new submission types and data elements our solutions are evolving and expanding right along with it.

Our intricate understanding of the FDA requirements enables our Regulatory Specialist Team to provide products and services that offer unparalleled speed and accuracy in the creation and migration of labeling documents to the SPL format.

Regardless of the kind of products you manufacture or distribute, we can transform your labels from any source format to SPL. Whether you are looking for a complete out-sourced service or interim SPL support during busy submission times, i4i has the solution that is right for you.

About i4i

i4i is a world leader in the design and development of structured content solutions and technologies. The company has a proven record of accomplishment and innovation, having authored international standards and patented its technology.

We focus on developing applications to assist the life sciences industry with their product documentation and regulatory information creation and management. Our solutions increase efficiency, consistency and support compliance through innovative, cost-effective and reliable technologies.

The i4i Advantage

Our SPL DIRECT services are delivered by experienced and knowledgeable regulatory specialists, using the industry leading technology of A4L - i4i's leading structured content platform. The combination of the A4L platform, experienced personnel, and a process-oriented testing methodology ensures quality and compliance e very time.

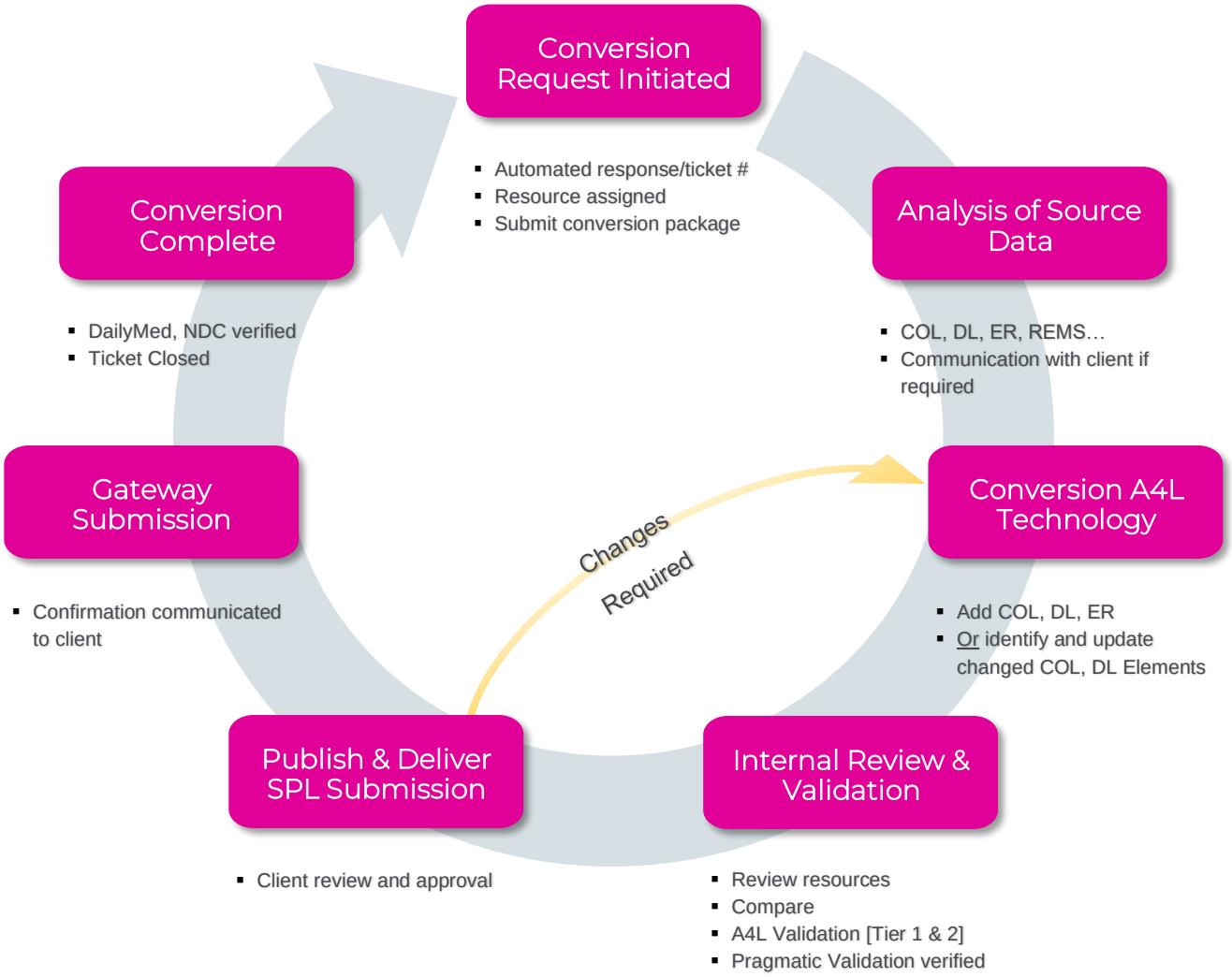
A4L's validation process verifies SPL files against the required schema, as defined in the SPL Implementation and Guidance documentation and provides in-depth validation using the FDA's SPL validation rules, including OTC Monograph/CRF rules, Medication Guide validation, required content of labeling sections, and UNII code and moiety validation. All of which ensures that the SPL will be submission ready.

Our processes support all FDA requirements & standards and ensure the validity and acceptance of your labels.

Methodology & Process

i4i's process-oriented methodology for SPL creation is well-defined and tested. It ensures character-level conversion accuracy and conformance to both the FDA's SPL standard and the ISO-governed XML standard.

Within this methodology is a high-quality process that includes the following steps:



SPL DIRECT: Compliance & Regulatory Services

- Establishment Registrations SPL creation and annual updates.
- Labeler Code Request SPL creation.
- Drug Listing/Content of Labeling SPL creation.
- Lot Distribution Report SPL creation.
- Generic Drug Facility Identification Submission.
- REMS SPL creation.
- Identification of CBER-Regulated Generic Drug Facility.
- ACA6004 [Drug Sample Reporting] conversions to XML.
- Gateway submissions: including error resolution and troubleshooting.

Contact i4i

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

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