Labelling Compliance Services for SPL

Fast, Accurate, Proven

At i4i, we can help you efficiently update your current SPLs and get them accepted upon submission. Whether you are looking for a complete outsourced service or interim SPL support during busy submission periods, i4i has the solution that is right for you.

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

i4i has been at the forefront as a leading contributor to the development of the US SPL format. As the guidance continues to evolve and be refined by Health Canada our solutions and expertise are evolving right along with it.

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 Compliance Services for SPL 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 every time.

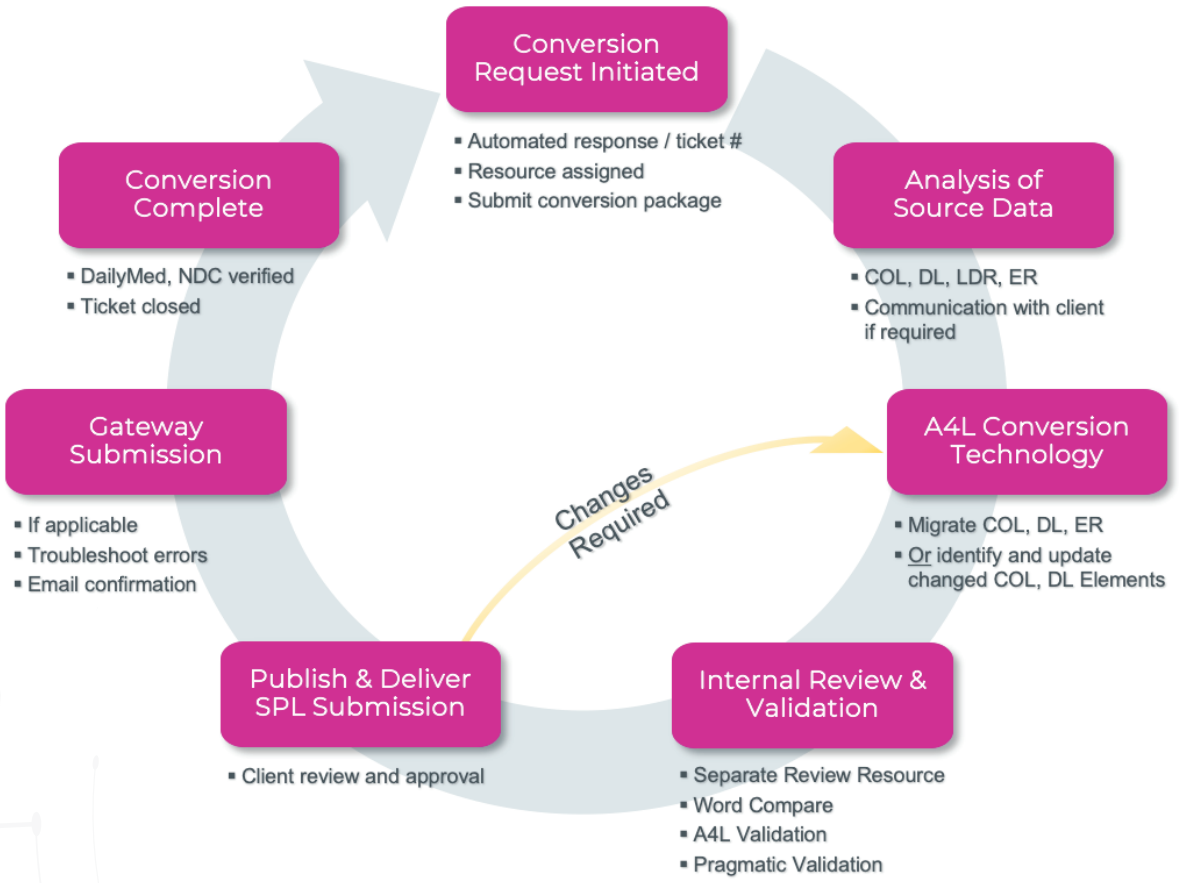
A4L's validation process verifies SPL documents against the required schema, as defined in the FDA's Implementation and Guidance documentation and provides in-depth validation using the FDA's SPL validation rules, including required content of labelling sections, and UNII code and moiety validation. All of which ensures that your SPL will be submission ready.

Our processes support all FDA requirements and standards, ensuring 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 format and the ISO-governed XML standard.

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



SPL Compliance Services: Compliance & Regulatory Services

- i4i's A4L software is validated for compliance
- Client data is stored on password protected machines within our internal network
- We retain data in a secure manor indefinitely, unless otherwise specified by our clients
- Active member of the FDA's SPL and HC's XML PM Leadership Team and various industry sub-committees since inception of the SPL standard
- Industry leading SPL and XML PM expertise
- SPL / XML PM Conversion Team members also train and support i4i's 90+ pharmaceutical clients
- Actively working with the FDA and US clients on SPL submissions
- Gateway submission error resolution and troubleshooting