Regulatory Assist

Labelling Compliance Services for SPL, XML PM & FHIR ePI

Fast, Accurate, Proven

At i4i, we can transform your current or legacy product labelling documents into the required standard; SPL, XML Product Monograph (XML PM), or FHIR ePI. Whether you are looking for a complete outsourced service or interim submission support during busy periods, i4i has the solution that is right for you.

Our intricate understanding of electronic standards requirements enables our Regulatory Team to provide products and services that offer unparalleled speed and accuracy in the creation and migration of labelling documents to the required format.

i4i has been at the forefront as a leading contributor to the development of the US SPL guidance and the XML PM format. We are also actively engaged with the Vulcan FHIR Accelerator group and a member of the ePI sub-group as the ePI FHIR standard is refined and implemented. As guidance for these standards continues to evolve our solutions and expertise are evolving right along with it.

About i4i

i4i is a world leader in structured content technology, delivering solutions and services for fast, accurate, and consistent submissions of globally regulated content.

Serving the life sciences industry for over 20 years, i4i has earned a reputation for excellence and thought leadership.

The i4i Advantage

Our Regulatory Assist services are delivered by experienced and knowledgeable regulatory specialists using the industry-leading technology of A4L - i4i's innovative 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 files against the required schema, as defined in Implementation and Guidance documentation and provides in-depth validation using best practices and defined validation rules. All of which ensures that your labels and leaflets are submission-ready.

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

Methodology & Process

i4i's process-oriented methodology for creating regulated labeling submissions is well-defined and tested. It ensures character-level conversion accuracy and conformance to the Health Authority's standard, the ISO-governed XML standard and HL7 SPL and FHIR specifications.

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

Regulatory Assist: 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 Vulcan FHIR Accelerator group, the FDA's SPL, and Health Canada's XML PM Leadership Teams, and various industry sub-committees since inception of the SPL standard
- Industry leading FHIR ePI, XML PM, & SPL expertise
- Our Regulatory Team also train and support i4i's 90+ pharmaceutical clients
- Actively working with Health Canada and Canadian clients on XML PM submissions
- Gateway submission error resolution and troubleshooting

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