

Labelling Compliance Services for XML PM

Fast, Accurate, Proven

i4i has been at the forefront as a leading contributor to the development of the XML Product Monograph (XML PM) format. As the guidance continues to evolve and be refined by Health Canada our solutions are evolving and refining right along with it.

Our intricate understanding of Health Canada's 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 XML PM format.

At i4i, we can transform your labels from any source format to XML PM. Whether you are looking for a complete out-sourced service or interim XML PM 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 Compliance Services for XML PM 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.

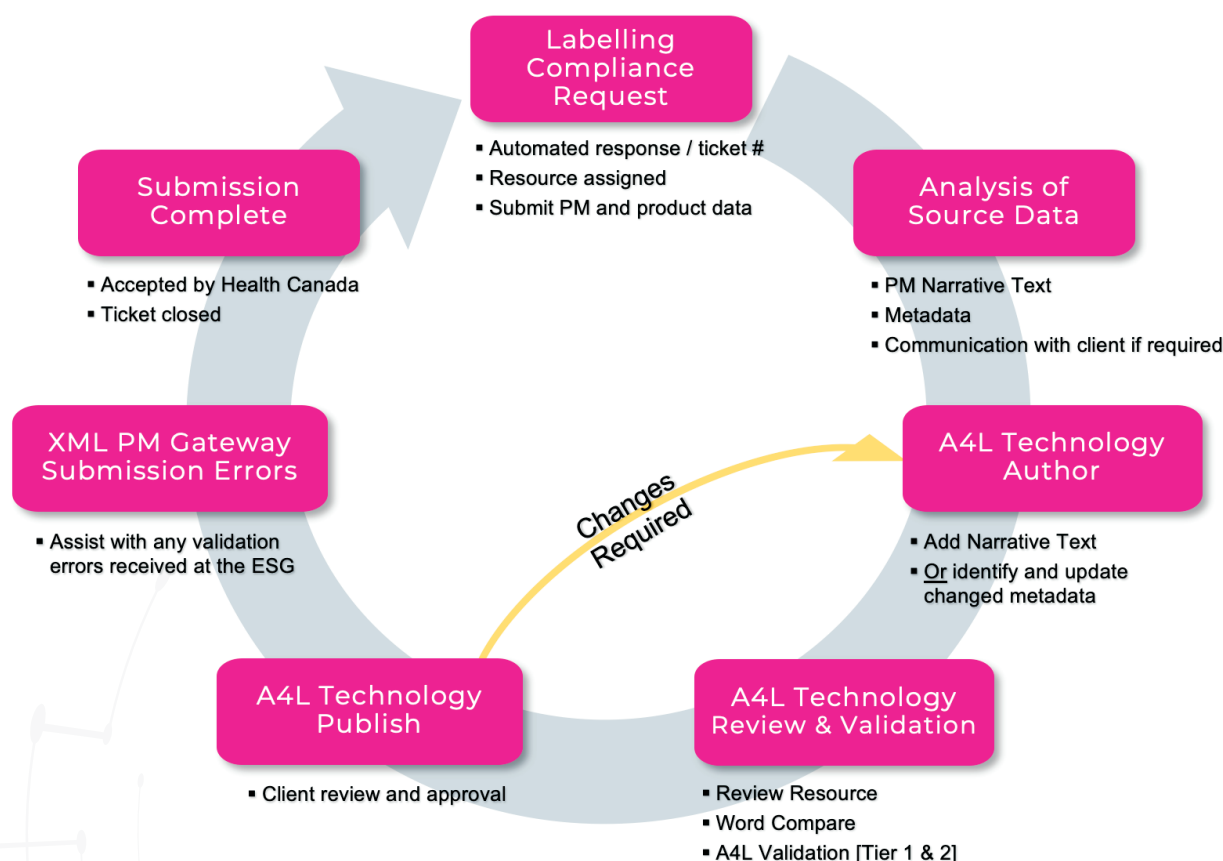
A4L's validation process verifies XML PM documents against the required schema, as defined in Health Canada's Implementation and Guidance documentation and provides in-depth validation using Health Canada's XML PM validation rules, including required content of labeling sections, and UNII code and moiety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

Our processes support all Health Canada requirements and standards, ensuring the validity and acceptance of your labels.

Methodology & Process

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

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



XML PM Compliance Services: Compliance & Regulatory Services

- A4L is installed and validated internally
- 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 XML PM and SPL expertise
- XML PM / SPL Conversion Team members also train and support i4i's 90+ pharmaceutical clients
- Actively working with Health Canada and Canadian clients on XML PM submissions
- Gateway submissions: including error resolution and troubleshooting.