REGULATORY DRUG LABELING

You Need Accurate, Compliant Drug Labels in All Markets. We Can Help.

You want to bring your drugs to market as quickly as possible, so you can expedite return on your R&D investments and deliver medicine safely and effectively to the people who need it most across the world.

Accurate and compliant regulatory drug labels are critical elements of an expedient go-to-market strategy. Regulatory compliance, accurate translation, and the correct use of standardized medical terminology, such as MedDRA and EDQM, facilitate correct drug administration, irrespective of the market or therapeutic indication.

What's more, global product launches often require translations into an overwhelming number of languages and layers of regulations with which to comply.

To ensure accuracy and compliance without sacrificing speed, you need a qualified Language Services Provider.

LIONBRIDGE

Make Lionbridge Your Global Compliance Partner

As a global linguistic service provider with extensive experience in drug label translations, we offer deep understanding of labeling requirements, procedures that ensure linguistic quality and regulatory compliance, and the linguistic capacity to support global or parallel drug launches.

Our solutions comprise the linguistic, therapeutic, and technical capabilities required to manage the complexities of drug labeling and to facilitate flawless submissions every time. Our services support:

- Regulatory product labeling, e.g. in accordance with EMA linguistic review processes
- Linguistic validation
- Dossier submissions and certifications
- Business Process Optimization
- Multilingual content management for full post-marketing product lifecycle
- Strategic consulting and project management
- Initial translation for core data sheets
- DTP formatting per HA regulations

Customer Results

We recently helped a top pharma company realize savings of multi-million dollars.

Hundreds
of dossier submissions to local Health Authorities

90+
Markets

10K+
Labeling Projects

10M+
Words Per Year

- **Their Challenge:** Address skyrocketing costs, limited scalability, and lack of IP control across internal teams and external suppliers.
- **Our Solution:** Our team signed on to deploy a fully-validated, centralized outsourced production model to ensure global compliance. Our Regulatory Affairs team identified multi-lingual product information and labeling documentation as areas to optimize cross-functional activities. By partnering with us, the client experienced significant cost-savings and improved efficiencies.

30%
Reduction in average turnaround time

15%
Annual savings over the internal model

100+
Internal FTEs successfully re-deployed to core tasks

The World's Largest Pharma, Medtech, and CRO's Partner With Lionbridge to Obtain:

- Partnership with a global provider capable of managing simultaneous submissions to multiple agencies
- Timely regulatory submissions/registrations
- Accurate and compliant translations of drug labels for all target markets and therapeutic indications
- Consistent label terminology
- Automated technology and human expertise that reduce errors
- A single partner that can streamline your process and reduce inefficiencies and noncompliance
- A flawless translation process that ensures readiness for submissions and relieves internal translation burdens

Get Started

Contact us today to talk with an expert and learn how Lionbridge can improve the adoption, usability and success of your global products and services.

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