LIONBRIDGE

GLOBAL REGULATORY SOLUTIONS
CLINICAL LABELING SERVICES

How integrated workflows and automation can transform your marketing organization

A patient's success with a regimen relies in part on their adherence to said regimen. And that success depends on their understanding—and their providers' understanding—of just what they're swallowing, infusing, applying, injecting, or implanting. And all of this relies on a very important piece of communications early in the process: clinical labeling.

Investigational Medicinal Products (IMPs) can only make it to their end users of developers and distributors if they can balance the jurisdictional variation in linguistic and regulatory requirements. This is where a Language Services Provider (LSP) can save time and money while reducing errors for anyone in the IMP pipeline. Find out how inside.

WE UNDERSTAND YOUR CHALLENGES

Clinical supply teams managing the clinical labeling in global studies are facing:

Shorter Production Timelines: From weeks to days for single panel labels

Errors and Inconsistencies: Multiple vendors across multi-center global studies lead to regulatory mistakes and translation errors

Demanding Process: Managing different vendors for different languages and tasks across study sites and geographies is a challenge for even the most robust organizations

Immediately reduce costs and turnaround whilst increasing quality with Lionbridge Global Regulatory Solutions. Centralize and simplify the clinical label regulatory validation and translation process.

Quality and Consistency

Our customers demand 100% error-free quality, and guaranteed outputs for the creation, translation, and regulatory review of their clinical labeling.

This process is on the critical path to a safe and successful study, and mistakes can be very costly.

Financially: Re-prints of labels, labels not approved by the authorities, studies invalid

In Terms of Safety: correct dosages, administration, storage, etc.

Lionbridge Life Sciences understands this. Working under our Clinical Labeling team, our SMEs and linguistic experts ensure our work meets our clients' requirements, with a right-the-first-time approach.

You shouldn't need to worry about how your clinical supply vendors operate. Expect your clinical labeling partner to be compliant with recognized quality standards and follow continuous improvement measures to always be up-to-date with industry best practice and regulation.

Lionbridge Life Sciences holds certifications in **ISO 9001:2015, ISO 13485:2016** and **ISO 17100:2015.**

Lionbridge Life Sciences is compliant with the appropriate requirements of **21 CFR Part 11.**

Resources and Global Reach

You expect your clinical labeling partner to have the network and resources to manage your global study labeling needs. You expect suitably qualified and experienced translators, and a network of regulatory Subject Matter Experts that covers all the regions and health authorities appropriate to your study sites.

350+ Languages

Lionbridge has access to a global translator pool able to translate medical and scientific content into over 350 languages.

100+ Countries

Specifically for clinical labeling creation and validation, we cover over 100 countries.

Lionbridge Life Sciences has a formal program maintaining training procedures and training records through our bespoke Quality Management System. We have strict minimum qualifications for all our linguistic resources and regulatory Subject Matter Experts. Our linguistic resources are constantly reassessed through quality checks and language quality inspections with each and every project they complete in a process known as perpetual evaluation.

Our Translators

- Educated to degree level (in translation)
- Highly responsive
- Native speakers of the target language
- Detailed
- Experienced in medical and pharmaceutical translation
- Linguistic experts

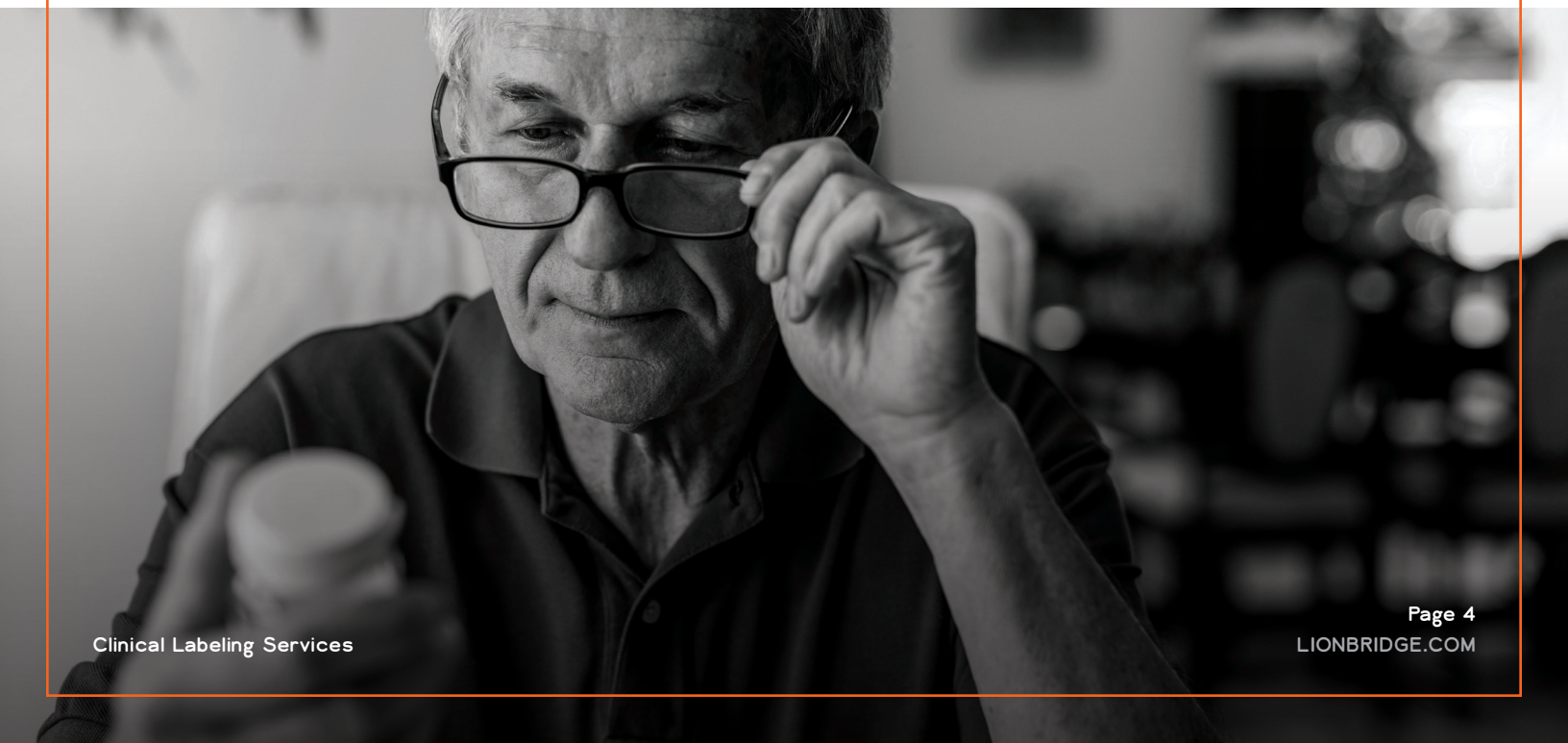
Our Subject Matter Experts

- Educated to degree level or higher (in Life Sciences)
- Knowledge of international and respective country-specific regulatory requirements for clinical labeling
- Experienced in the domain of Regulatory Affairs

Our Subject Matter Experts maintain current knowledge of the continuously evolving published guidelines and guidance of the global Regulatory Body and Health Authority network, at a regional and local levels.

Lionbridge Life Sciences continuously monitors and develops our entire network of resources to ensure a best-in-class level of service and suitability. All resources are reassessed at regular intervals.

We maintain a central database of local and regional regulatory rules. Our team combines translation and regulatory validation services. We maintain regulatory and linguistic consistency and compliance across all markets and languages.



OUR CLINICAL LABELING SERVICES

Are you looking for a partner to manage the translation of individual labels on an ad hoc basis, or a full-service label regulatory validation and translation offering?

Regardless of your needs, we have the experience, network, and flexibility to make it happen. From a single label in a single market, to multiple labels across 100+ countries simultaneously.

We work with leading Pharmaceutical, Biotechnology, Clinical Research Organization (CRO), and Contract Manufacturing Organization (CMO) companies to efficiently create, develop, and validate labels to be used in global clinical trials.

Flexibility is at the core of our "Label Creation and Validation" solution, as we are in a unique position to handle all steps of the process. Starting with an English Master Label or study protocol, we can deliver back fully validated and localized clinical labels. We can also create English Master Labels on your behalf from study protocol documents.

Customers can also select specific services from our portfolio, according to their needs for standalone services, with best-in-class turnaround times:

Subject Matter Expert Regulatory Review and Validation

Global coverage for IMPs in all markets

Translation

Over 100 languages for clinical labeling

Back-Translation, Comparative Review and Reconciliation: Best practice and regulatory compliance

Label Proofing: Proofreading of the formatted label before it is sent to the printer

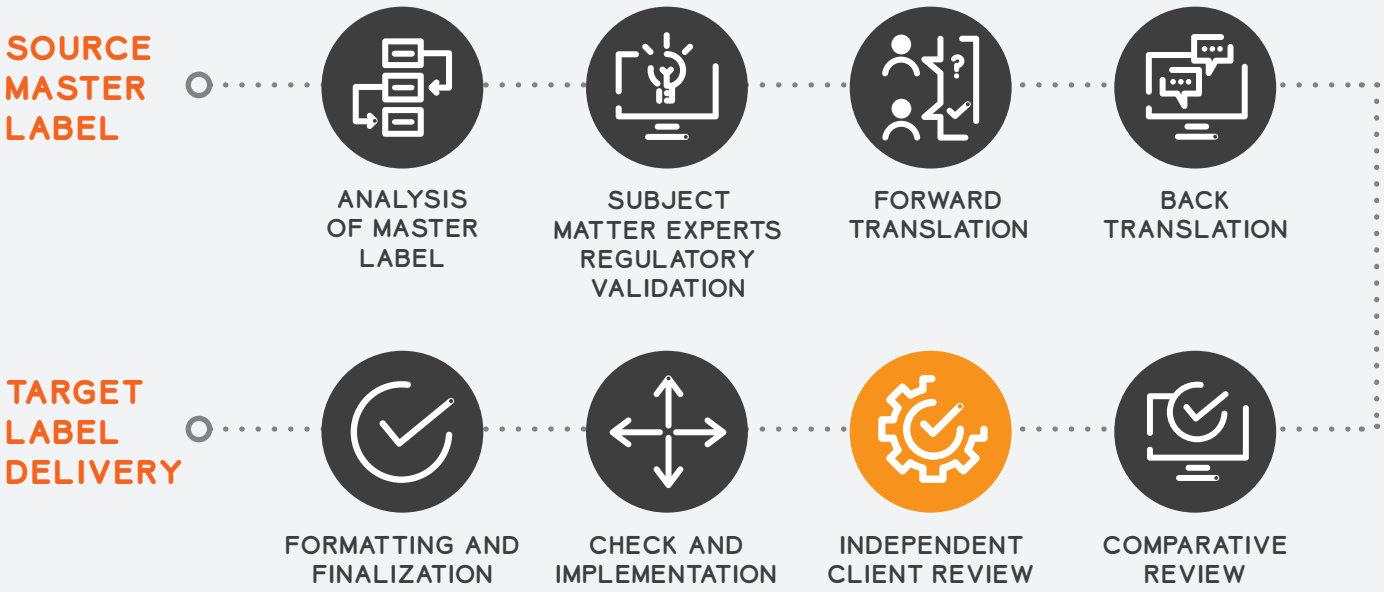
Formatting: Multiple label formats for any product or container

Finalization: Label regulatory validation and translation with certification

Project Management: World class project management to optimize your internal resources capacity

Our core offering is a fully customizable workflow for label text creation, translation, and validation. It is documented and controlled through strict internal Standard Operating Procedures (SOPs), and fully compliant with regulatory guidance. Additional services are based entirely around your specific needs and requirements and include:

- English Master Label Creation
- Phrase Library management and maintenance across all client studies
- Including historic Phrase Library re-validation and correction
- Maintenance of country-specific internal regulatory information pages



Dedicated Project Management Teams and Customer Support

The connection our customers have with their Lionbridge Project Management teams is vital for successful partnerships. You will have:

- Dedicated Subject Matter Expert Project Management teams, spanning the globe and sitting within our Lionbridge Life Science Centers of Excellence, solely focused on clinical labeling work
- Best-in-class customer support and query handling
- Documented escalation process
- Corrective Action/Preventative Action (CAPA) process covered by SOPs and compliant with 21 CFR Part 11 and ISO 13485
- Regulatory domain experience

When it comes to clinical labeling, you need experience in both pharmaceutical regulations and translation. Our experts can fill the gaps in your knowledge and streamline operations with years of project management expertise.

Get in touch with our Clinical Labeling team today to find out how Lionbridge can support your group from start to finish in any market.

About Lionbridge

Lionbridge partners with brands to break barriers and build bridges all over the world. For 25 years, we have helped companies connect with their global customers and employees by delivering translation and localization solutions in 350+ languages. Through our world-class platform, we orchestrate a network of passionate experts across the globe who partner with brands to create culturally rich experiences. Relentless in our love of linguistics, we use the best of human and machine intelligence to forge understanding that resonates with our customers' customers. Based in Waltham, Massachusetts, Lionbridge maintains solution centers in 23 countries.

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