BIOPHARMACEUTICAL CLINICAL LABELING CASE STUDY

LIONBRIDGE

CLINICAL LABELING CASE STUDY OVERCOMING CLINICAL LABELING TRANSLATION CHALLENGES

18% RUSH ORDERS

36 LANGUAGE PAIRS

99.3% OF TRANSLATION PROJECTS DELIVERED ON TIME 50% FASTER DELIVERY THAN INITIAL CUSTOMER AGREEMENT

The Challenge

Lionbridge had three significant challenges in assisting our customer. The first challenge was handling technical issues posed by four languages in particular: Hebrew, Thai, Korean, and Japanese. Hebrew is read from right to left, versus languages with Latin characters (like English), which display from left to right. The IMP labels had a mix of Hebrew and Latin characters in this case. This presented a unique challenge for correctly processing both kinds of text. Specifically, the Hebrew containing signs (slash, hyphen, etc.) or English text was not always processed correctly by the customer's system.

The second challenge was related to usage of three Asian languages: Thai, Korean, and Japanese.

Frequently, translations into these languages expand on or lengthen the text. This expansion can make it challenging to fit the new text into the typically allotted single line on the label. The customer needed help deciding where to divide the text, so it could fit in the appropriate spacing on the label.

The third challenge was meeting our customer's tight deadlines. In 2022, almost 20% of all its Lionbridge projects were rush orders. We processed rush orders within two working days, rather than the typical four working days. The rush orders helped the biopharmaceutical company complete trial start-up activities faster. We created labels for studies commencing in a tight timeframe or with tight regulatory deadlines to meet.

About the Customer

Our customer, headquartered in the U.K., is a global biopharma company. Their mission is to help prevent and treat disease. One of the largest biopharmaceutical companies in the world, this customer focuses on infectious diseases and oncology, amongst other areas. They develop innovative specialty medicines and vaccines via deep research methodology, expertise in the human immune system, and advanced technologies.

Lionbridge has proudly supported them since 2016. We have offered services across a variety of areas supporting clinical studies, including translating label phrases for its Investigational Medicinal Product (IMP) labels.

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The Solution

Lionbridge has served our valued customer in three main ways.

Firstly, Lionbridge ensured easy access to the translated text. We delivered translations to our customer in Excel files organized by language. We also provided translated text in XML translation files. This format of the deliverable was needed. as English Master Phrases may contain variables (XML tags). They're used to indicate temperature values, drug name and strength (mg/ml, etc.), and amounts. At run time, they're substituted with the actual value. These XML tags are very long and complex. To keep the phrases readable for the client, the tags are replaced by color-coded placeholders in the final Excel deliverables using the customized technical solution. This format allowed for easy importation of the files directly into our customer's system. Our process facilitated accurate, structured handover and transfer of translated content from Lionbridge to the biopharmaceutical company.

The second part of Lionbridge's solution was handling the specific challenges posed by text in Hebrew, Thai, Japanese, and Korean. Lionbridge inserted special Unicode control characters in the target phrase for labels requiring Hebrew and English text (or text including signs). These characters denoted the start and end of text that went from left to right, or right to left. They defined the correct order of elements for our customer's system. Lionbridge then delivered translated files via Lionbridge La'nguage Cloud[™]. Additionally, Lionbridge developed a special script to identify "forbidden" Hebrew characters. "Forbidden characters" were never correctly displayed in the customer system, and thus were replaced with more accurate characters. After the translated content was imported into our customer's system, they generated a translation file in PDF format. We used that PDF file to confirm the translation displayed without errors. This iterative process ensured the final translated text was integrated and displayed.

Together with our customer, Lionbridge developed a new, optimized communication workflow to improve process agility and efficiency. When they submitted a clinical labeling translation request in one of the above-listed Asian languages, our customer informed Lionbridge if it included a long target phrase. Lionbridge asked our target language specialists to provide options for line breaks in the phrase. We added these possible line breaks in the final deliverables. These additions helped the company choose and utilize correct line breaks during the label creation phase. Notably, they never had to waste additional time requesting them from Lionbridge.

The last way Lionbridge supported our customer was by helping them meet very tight regulatory deadlines. **Even though almost 20% of their projects were rush orders, Lionbridge still delivered 99.3% on time. Our delivery was generally 50% faster than the "standard" turnaround that the customer and Lionbridge initially agreed upon. We also delivered 19.8% of projects early.** When we delivered early, it was typically one to four days before the scheduled delivery date.

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Multidisciplinary Team

- 1 Senior Project Manager
- Backup Senior Project Manager
- 2 Project Managers
- 2 Language Leads
- Account Executive
- 🖞 Lionbridge Global Program Manager

COMMUNICATION

Quarterly business reviews



Ad-hoc calls as needed

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The Results

Lionbridge helped our customer realize a few impactful outcomes. Critically, we enhanced their language quality process. Our procedures dramatically reduced translation errors. In the last year, Lionbridge delivered at a **99.85% error-free rate.** This reduction in translation errors enabled our customer to produce more accurate clinical labels in **36 target languages,** including Hebrew, Thai, Korean, and Japanese.

A second result was that our customer was able to execute on clinical labeling needs more efficiently — even in 36 languages. With a more efficient clinical labeling process, they could easily meet the rigid deadlines imposed by various regional regulators. Ultimately, this helped them distribute their IMPs faster for clinical research.

Overall, Lionbridge's efficient management of clinical labeling translations and white glove service has helped our client pursue their mission to make the world a healthier place.

BY THE NUMBERS 36 Target Languages in 2022, 678 Phrases 7 Years of Including: Hebrew, Thai, Partnership Translated in 2022 Korean, Japanese 50% Faster Delivery 18% Rush Orders 99.3% of Translation than Initial Customer **Projects Delivered** Agreement on Time





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