



## Translation of New Drug Applications for the FDA

This client is one of the leading pharmaceutical firms in China's biotechnology and biopharmaceutical sectors. To ensure the quality of each batch of drugs, the company strictly implements international quality standards for drug production. Such emphasis on quality means that the company is equally demanding when it comes to the quality of translations of drug registration submissions, and does not hesitate to cease partnerships with language service providers when there are quality issues. After a rigorous selection of translation providers, the company chose EC Innovations for new drug applications to be submitted to the FDA.



## Challenges

Due to increasing quantities of new drug registrations, the company's previous language service provider was unable to meet its high quality requirements and turnaround time expectations. Not only did this result in significantly increased workloads for the company because of the extent of internal reviews required, submissions of new drug registrations by the company were potentially delayed further. The company needed a translation service provider with extensive experience in the translation of drug registrations and an efficient project management workflow to ensure its new drug applications were processed smoothly.

# WHY EC INNOVATIONS?

## CASE STUDY

### Qualified Translation Team



EC Innovations formed a qualified translation team for the client, including professional native-speaking translators, senior editors and proofreaders in the field of drug registration, ensuring the translations would be of the required accuracy for FDA submissions.

### Quality Assurance



**Pre-project research and briefings:** To ensure accurate translations of the client's new drug registrations, the translation team at EC Innovations pre-empted topical and technical challenges by conducting research, holding group discussions, participating in briefings by experts, and requesting consultations with the client. By taking these measures, EC Innovations ensured that its translations for the client would meet submission requirements.

**Glossary verification and maintenance:** Drugs are consequential for the life and health of patients, so the FDA is undoubtedly stringent in its reviews of new drug applications. Therefore, accurate translations of terminology are of the utmost importance. Our translation team extracted terminology to be used for the project from databases and merged it with those provided by the client. The overall project terminology list was then submitted to the client for verification. This ensured that accurate and specialized terminology was used in translations of new drug applications. Additionally, we provided the client with systematic solutions for language asset management and maintenance, to fulfill the client's requirements for consistent terminology that would arise in later stages.

**Layers of checks for top-quality translations:** On top of native-speaking translators in the field shortlisted by EC Innovations, third-party reviewers were also arranged upon the client's request, thereby adding an additional stage to the usual project workflow for quality controls of TE + QA + DTP + proofreading. Layers of checks ensured specialist terminology, accurate expressions, and suitable sentence structures and grammar were used in the translations of new drug applications. Such high-quality translations helped reduce the amount of time and effort that the client needed to spend on internal reviews.

## Fast Delivery



EC Innovations' Localization Process Automation solution (TBMS-LPA) optimized the client's multilingual project workflows, which in turn ensured that the client's new drug registrations were submitted smoothly as planned. The TBMS-LPA solution made automated file transfer and processing, automated project operations, online translation, and online QA possible. Multithread and barrier-free collaboration was facilitated for the working project team through integrated Cloud-CAT tools and MT management tools, minimizing time spent on back-and-forth file exchanges and project management.

## RESULTS

The combination of EC Innovations' 21-year track record in pharmaceutical translations and localization, experience with the drug manufacturing industry, and project-specific internal briefings enabled timely deliveries of translations in line with the client's expectations in specialist writing, terminology accuracy, and localization.

Through automated translation and project management, EC Innovations managed to surpass the client's expectations by enabling an increase in productivity and a nearly 30% savings for the client.

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