

CASE STUDY

Not Just a Vendor, But Part of the Team

**CUSTOMER SERVICE EXPERIENCE
COUPLED WITH LEADERSHIP IN
TRANSLATION MANAGEMENT =
A RECIPE FOR SUCCESS**



The challenge: lengthy label timelines and rapid pipeline growth

An emerging biotechnology company was at a point where timelines to get label text approved and in place was pushing almost 6 months for every study. At the same time, they were in a period of tremendous growth and understaffed to manage an ever expanding portfolio. During this tumultuous time, the company would schedule packaging dates and regularly miss them because labels were not ready. Investigator sites expressed their unhappiness with the excessive patient rescheduling and resulting loss of patients, and indicated an unwillingness to participate in the study.

To manage the label translation process, the company created an internal spreadsheet of approved phrases for each language, as well as individual label mock-up for each job. Despite these best efforts to try and manage creation of master English text and translations, the process was overly time-consuming and error-prone. In addition, the company relied heavily on multiple third party vendors to support its label proof creation and manufacturing efforts. With multiple vendor relationships to coordinate, coupled with internal manual management of phrases, labels had become a significant bottleneck.

The solution: AtlasSM translation management services

Frustrated by lengthy clinical timelines and unhappy sites, the company reached out to the Thermo Fisher Scientific team to help find a solution. They reviewed the situation and proposed utilizing the ATLASSM Translation Management Service to develop an electronic library of approved label phrases, built and managed by experienced Thermo Fisher Scientific project managers that provided the ability to store and auto-populate country specific regulatory requirements.

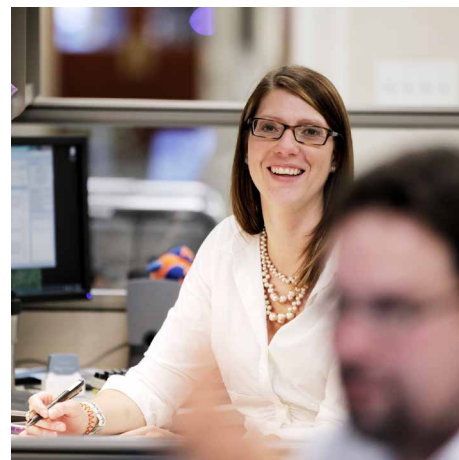
The first step for onboarding to the ATLAS system was working with the Thermo Fisher Scientific team to develop an approved phrase library within the ATLAS database, as well as establishing standard client job requirements such as sizing and design standards. Once established, the sponsor reduced cycle times for label text approval and booklet label generation by over 4 months.

To further enable an optimized and integrated supply chain, the sponsor rewrote their internal SOP's to support the standard use of the ATLAS Translations Management System, and to further streamline communication between the two organizations.

The experience: personal and consultative project management

In the midst of all of this development it was decided to assign a dedicated Lead Project Manager to better assist the company in meeting the needs of its expanding pipeline and developing comprehensive global supply strategies that optimized drug supply and distribution channels.

With over 15 years' experience working in client services, this lead project manager served as the primary point of contact for the sponsor and worked with an internal team of Thermo Fisher Scientific Project Managers and Project Support Associates to ensure seamless execution of each job, from start to finish. Along with her team, and supporting departments, she was able to provide detailed, focused services tailored to their needs. She did this by:



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- Meeting with the company team face-to-face immediately after being assigned to the client, allowing her to get to know their personalities and preferences
- Revising their customer profile and fine tuning their requirements down to the smallest detail
- Reviewing upcoming projects as well as current and previous projects to learn about their successes and failures.

The Thermo Fisher Scientific team was able to provide guidance on everything from label applications and expiry update label strategies to master randomization creation and management, working with the company's clinical logistics team to maintain blinding.

The results: not just a vendor, but part of the team

With the Team Lead Project Manager leading the way, labels are ready several months in advance of all other supplies, sometimes including the drug. Label availability has helped drive efficiencies for the company, having them deliver their product to market sooner. Their collaboration with Thermo Fisher Scientific has provided comfort knowing their projects will be delivered on time or early without issues.



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