



LANGUAGE
SCIENTIFIC

Case Study

Biotechnology Firm

Ensuring FDA Approval for a Life Sciences Company

Problem

A leading human therapeutics company in the biotechnology industry was working with a German contract manufacturer who needed to document every change made in the drug manufacturing process from German to English. In order to achieve FDA approval for such drugs all documents were required to be translated and not only be linguistically accurate but also conform to strict guidelines including formatting details. These documents needed to be submitted to the FDA in a timely manner and comply with the standards of this highly regulated industry. Deviations from these guidelines can result in major delays and finding a vendor that could complete the project accurately and timely was critical.

Solution

On a weekly basis various documents were translated including:

- Process documents
- Master batch records
- Deviation reports
- Deviation summaries
- Deviation notification
- EM summaries.

Through the use of specific document templates, Language Scientific was able to improve the process and ensure documents remained consistent throughout the course of the project. Language Scientific's use of custom glossaries and translation memory software as well as strict quality assurance procedures help to streamline the process and ensure accuracy throughout the project. Language Scientific's Life Sciences division understood the degree of quality and accuracy required for such a project and were able to meet all necessary goals.

Benefits

Working consultatively, Language Scientific was able to provide significant value to the overall project success.

- ✓ Accurate translations helped ensure FDA approval
- ✓ Demanding timelines were met ensuring on-time delivery to market
- ✓ Use of advanced technology tools reduced translation costs
- ✓ Creative problem solving improved consistency

Client Quote

"Obtaining FDA approval in a timely manner is a necessity in bringing our products to market. This can be a tedious and lengthy process but when a project is managed properly and the translation is accurate, acceptance is much smoother,"

Senior Quality Control Manager

Contact us today to discuss how Language Scientific can meet your translation needs
617-621-0940 info@languagescientific.com www.languagescientific.com