TRANSPERFECT LIFE SCIENCES
CASE STUDY: GENENTECH AND NOVARTIS

In order to submit a new drug treatment for approval by the FDA, a leading biotechnology development firm needed over 1,000 pages of documentation translated under pressing deadlines and strict regulations. By employing our stringent quality management system and leveraging a substantial translation memory database, TransPerfect ensured that the intricate formatting of the content was maintained and that the translations met all regulatory standards for quality. The project was completed ahead of schedule, and the company succeeded in obtaining FDA approval for the drug.

The Client

Recognized as a leader in the field of biotechnology development, Genentech uses human genetic information to discover, develop, manufacture, and commercialize biotherapeutics that address significant unmet medical needs. The company partnered with Swiss-based Novartis Pharmaceuticals, a world leader in healthcare product development, in order to introduce Xolair, the first IgE blocker developed to treat the symptoms of allergic asthma.

The Challenge

Genentech and Novartis had invested millions of dollars into the development of Xolair. With FDA approval, their groundbreaking new drug could be made available to thousands of asthma sufferers across the United States; this, in turn, would generate millions of dollars in revenue that would fund additional research. However, because Novartis' master batch records were written in French, the partners found themselves with over 1,000 pages of documentation that needed to be translated in order to submit the treatment to the FDA for approval. And due to the pharmaceutical industry's stringent regulations that require superior translations employing consistent, accurate terminology, the translation process promised to be complex.

The TransPerfect Solution

Genentech looked to TransPerfect to meet their language needs for the Xolair project. The company had developed a solid relationship with us over a number of previous high-value projects. As a result, we had a substantial translation memory database comprised largely of highly technical, regulatory-related terminology. The linguists were able to refer to this database and leverage previously established client-approved terminology, ensuring consistency and accuracy throughout the 150,000 words that were translated from French into English. Additionally, through TransPerfect's ISO 9001:2000 certified, three-step translation, editing, and proofreading process, intricate and critical formatting of the source material were reflected in the end product. This attention to detail proved critical, as submission to the FDA requires a rigorous and thorough representation of the original text.

TransPerfect delivered the translations ahead of schedule, giving the two companies ample time to prepare the documentation for submission to the FDA. In the end, Xolair achieved approval and has treated tens of thousands of patients in the United States. This project led to the strengthening of TransPerfect's relationship with Genentech and the creation of a new relationship between us and Novartis. Both companies continue to rely on TransPerfect for dynamic language solutions to help bring their innovations to the market.

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