

Case Study # 2 Genentech



TRANSCENDING EXCELLENCE

Background: The #1 **biopharma** company in the U.S. needed 450 French case reports consisting of approximately 195 pages each, translated, formatted in English, certain fields in their SAS database populated, and then linked each page of English back to the original French page for an electronic filing with the FDA in 6 months.

Client Objective: To manage, translate, edit, format, proofread and link 22,000,000 medical words and 87,750 pages in 180 calendar days.

Challenge: The client provided the information on CD's with pdf files. Our first order of business was to have one of the case reports translated, edited, formatted and returned to the client for approval. Once approved, we developed a CRF template for the translators to use wherever applicable. The work was then assigned to our extensive network of medical translators and editors.

Because of the short time constraints and the fact that the formatting of this project was as large as the translation phase, we ramped up by renting 12 additional computers, acquiring a short term lease on adjacent office space and hiring 12 additional word processing staff. The dedicated Project Manager and team also moved their offices into this adjacent space to manage the project and staff.

Solution: The Project Manager developed and implemented a linear work process that insured consistency and accuracy without sacrificing turnaround time. // can we link thru file names?// She also had daily communication with the client and helped establish incremental deliverable

CHALLENGES:

- × Finding a partner with FDA regulations experience
- × Dealing with and processing massive amounts of clinical case reports

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deadlines which we met and exceeded at times. The PM also coordinated with our regular staff to facilitate the proofreading and SAS database aspects of this project.

Result: Working closely with the Client during each phase of the project provided the flexibility they required and left sufficient room for changes and updates without compromising the success of the project. Because of our advanced planning, our excellent project management team, our extensive network of translators, editors, and production staff, plus our ability to “ramp up” for large projects, we were able to not only meet our client’s deadline with quality translations, but furnish them with documents that were ready to be submitted as part of the first electronic submission involving translation to the FDA.

OUR SOLUTION:

- × Translated documents submitted online direct to FDA
- × Centralized solution with a single point of contact

About Phoenix Translations: Phoenix Translations is a leading provider of language translation and localization services. Through the unique combination of its Linguistic Quality Assurance (LQA) and Visual Quality Assurance (VQA), expert linguists and integration capabilities, Phoenix Translations services are designed to help clients quickly and easily secure the very best multilingual Web sites, technical documents in any language, and other global communications. Since 2000, the company has earned a reputation among its clients for reliability, quality and professionalism. Clients include: Kodak, MedImmune, Genentech, Exxon, and Johnson & Johnson as well as many law firms, and other major pharmaceutical and technical companies.