

Case Study

Pharmaceutical Company

Translating Handwritten Case Report Forms

Problem

A leading diabetes care company and producer of insulin needed patient case report forms translated from Japanese into English as part of a new drug application process. On-time submission of these documents was mandatory for FDA review and approval, and the translation schedule was tight. The major obstacle was that the documents were handwritten in Japanese and needed to be quickly and accurately translated into English. The company was concerned about document accuracy due to previous vendor errors and needed confidence that Language Scientific could provide accurate translations and meet necessary FDA deadlines. Missed deadlines would negatively impact the eventual marketing of the product and handwritten notes proved difficult for their previous translation provider, preventing accurate translation of source documentation.

Solution

Language Scientific's experience with patient case report forms and the life sciences industry enabled us to complete the work within the required short turnaround time and help the client meet critical FDA deadlines. Due to the specialized medical content of the case report forms, Language Scientific assigned doctors as translators to ensure accuracy and eliminate any deadline delays. From previous experience with handwritten documentation, Language Scientific developed and added a custom quality assurance process that specifically addressed handwritten doctors' notes. Language Scientific's experience had found that pairing native English linguists with local clinical professionals yields the most accuract possible translation for challenging handwritten material.

Benefits

Language Scientific was able to provide significant value to the overall success of the project by working consultatively with the client.

- Custom quality assurance steps saved the client internal time for document summary
- Language Scientific's experience with handwritten case report forms provided highly accurate documents
- Team of medical translators were able to meet critical deadlines
- Use of local, native speaking clinical professionals improved the quality of translation

Client Quote

"I am highly appreciative of Language Scientific's work on this project. The team worked tirelessly to meet what at first appeared to be an impossible deadline. I look forward to working with your company in the future as I am now very aware of what you can deliver."

Director of Regulatory Affairs

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