CASE STUDY

Accelerated transfer of bioanalytical methods from PPD Richmond Lab to PPD Suzhou Lab in China

BACKGROUND

The Chromatographic Science Department (CSD) of PPD Suzhou Bioanalytical Lab in China has transferred a large number of bioanalytical methods from PPD Richmond Lab since 2021, to support clinical PK and PD studies in China for global sponsors.

A leading pharmaceutical company planned on transferring a Hybrid LC-MS/MS PK method and a Hybrid LC-MS/MS biomarker method from Richmond Lab to Suzhou. The two methods were fully validated in Richmond, but the methods were difficult, and the experimental steps involved were tedious. The sponsor's clinical trial in China was required to be conducted in a very short time frame, allowing limited time for methods transfer.

The related team of PPD's Suzhou Lab and Richmond Lab worked together, communicated actively, arranged the project time reasonably, conducted detailed analysis of the technical difficulties involved, and transferred the methods under a significantly accelerated timeline.

OBJECTIVE

- Set up instrumentation for the methods.
- Timely completion the Hybrid LC-MS/MS PK method and Hybrid LC-MS/MS biomarker method transfer.
- Optimize and validate the methods to meet the requirements of Chinese regulations.
- Complete method cross validation prior to sample analysis.
- Initiate sample analysis under significantly accelerated timelines

CHALLENGES

- Limited time to complete the transfer, validation and cross validation of the two methods.
- Special sample extraction equipment was required.
- Long sample processing process for two methods increased the risk of contamination and operational errors.
- Procurement and transportation of key reagents and consumables was required.
- Specificity testing was needed with some patient matrix.
- Rapid import of quality control samples and study samples for cross validation was required.
- Assisting the sponsor with HGRAC clinical trial applications in a short time frame was required.

SOLUTIONS

- Bioanalytical CSD project manager was assigned to complete the overall project plan.
- Regular communication channel was established between Richmond and Suzhou Labs.
- Utilized existing instrumentation rather than special instrumentation.
- Prior to the method transfer, the Richmond Lab and Suzhou Lab discussed the technical intricacies of the analytical methods in detail. This was done to ensure that the key experimental steps were correct and close communication was maintained during the method transfer process.

- Conducted an e-mail award notification before the project contract was officially signed to start the procurement and transportation of key reagents. Some reagents were purchased by Richmond Lab and shipped to Suzhou to shorten the procurement cycle.
- The clinical institutions in China were contacted to urgently recruit patients for special matrices.
- Since the human matrix samples were imported into China, Suzhou Lab had to attend the CIQ (China Entry-Exit Inspection and Quarantine) meeting, respond to the meeting and after passing, obtain the import license. The entire application process takes one to two months. Thus, the preparation of cross-validation sample import materials was started early in the process of methods transfer period. The import license was obtained at the beginning of the method validation, and the samples were imported. After the method validation was completed, the cross-validation samples were received in time to carry out the cross-validation study.
- A dedicated staff member in Richmond coordinated the transportation of reagents and cross-validation of the samples in Suzhou to reduce the timeline.
- The Suzhou Lab designated someone to assist with HGRAC applications to expedite the application process.

RESULTS

The transfer of the Hybrid LC-MS/MS PK method and the Hybrid LC-MS/MS biomarker method from Richmond to Suzhou was completed successfully and on time in an accelerated manner. The validation and sample analysis were able to meet the requirements of Chinese regulations. The cross-validation results from the Richmond and Suzhou Labs met the data acceptance criteria, demonstrating the consistency of the two Hybrid LC-MS/MS methods between the two laboratories. At the same time, the sample analysis results were in line with expectations. Through effective communication and reasonable project coordination, we were able to accelerate the method transfer and establish a rapid method transfer process, that facilitates the rapid development of clinical trials in China.

PPD Laboratory services in Suzhou, China helps customers make faster and more accurate decisions and accelerate their studies through global standards of high-quality data and convenient local services. With an integrated laboratory, you will have access to an in-country facility with all the same PPD capabilities.

With in-country kitting, the latest instrumentation and high-throughput automation, our Suzhou lab is equipped with the tools to provide high quality results and data for your studies.

PPD® Part of Thermo Fisher Scientific