Bioanalytical Lab Capability

Accelerated method transfer of PK, ADA and Nab assays from PPD Richmond Lab to PPD Suzhou Lab in China

BACKGROUND

The need for the globalization of clinical trials is growing due to the objective scientific need to conduct clinical trials simultaneously in multiple regions of the world PPD™ Suzhou. Resulting into the increasing complexity of regulatory compliance requirements and the rising cost of various materials and manpower. PPD Suzhou Laboratory was established to provide highly efficient, high standard and high-quality laboratory testing services to accelerate global clinical trials and drug commercialization in China.

PPD Suzhou Immunochemistry Department (ICD) can support the method transfer of PK, ADA and Nab assays for large molecular drug from other labs, especially from our Richmond lab. The Suzhou team has close coordination and communication with the Richmond team, which can help to make the method transfer more successful and effective within a short period of time.

OBJECTIVE

- Assist the sponsors in importing the critical reagents and materials.
- Optimize and validate the methods to meet Chinese regulatory requirements.
- Complete method cross-validation within different labs to demonstrate method consistency.

CHALLENGES

- Different batches of labeling reagents vary widely.
- Different human matrices and general reagents could lead to inconsistent results, requiring time to optimize the method.
- Need to import samples and cells for cross-validation.
- Transfer and validate multiple methods for a project and coordinate with different departments in a very short time.

SOLUTIONS

- Assigned an ICD project manager to oversee the whole bioanalytical work, assigned PIs (Principle Investigator) immediately after contract award.
- Set up a kick-off meeting with sponsors, Richmond and Suzhou lab personals to discuss the project background, potential method transfer risks and study timeline before lab work started. Communicated closely with Richmond PIs during method transfer and validation.
- Designated a person in PPD Richmond to be responsible for assisting the Suzhou lab in organizing reagents shipment and coordinating with Richmond PIs to complete the method cross-validation.
- Assigned very experienced import and export staff, who could support the import and CIQ (China Entry-Exit Inspection and Quarantine) assessment rapidly with 100% success rate.
- Labeled a large pool of reagents by PPD Richmond lab and shipped to PPD Suzhou lab. Used the same lot to perform

RESULTS

By working closely with PPD Richmond team, PPD Suzhou lab received the reagents of PK, ADA and Nab assays within a short time after the method was finalized in PPD Richmond lab. When the method transfer results of PK assay were found to be unstable, Suzhou PM and PI reported the data and discussed with PPD Richmond PI and the sponsor in time and quickly optimized a stable method within 1 week.

ADA' s method transfer was completed within 2 weeks of receiving the reagent, and the results were consistent with Richmond's.

The Cell-based Nab method established the stable cell bank pool within 1 month and also achieved results consistent with the original method as well. All methods were completed validation within 1 month.

After validation, the Richmond team discussed cross-validation with the sponsor and the Suzhou team and quickly completed the sample preparation. With the help of the import and export staff at Suzhou, the Suzhou team immediately applied for CIQ and received CIQ approval in the second month. The cross-validation samples were shipped and received in Suzhou lab in the same month. The PIs arranged cross-validation experiment in advance and the analysts conducted the cross-validation after receiving the sample.

All results met the acceptance criteria of the cross-validation compared with the results of Richmond lab, demonstrating methodological consistency between the different laboratories.

The entire method transfer and validation process took approximately 4 months and was well received by the sponsor. Throughout this project, effective and close communication accelerated the method transfer period. And professional import and export personnel are critical to the timeline for the launch of the experiment, and experienced PIs and analysts can expedite the completion of experiments.

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