

Case Study

Tech Transfer China for IFE Reflex Assay

Scope

Biotech Company in China required our scientific expertise for the Tech Transfer of IFE Reflex Assay on a clinical trial in the Oncology field (Relapsed or Refractory Multiple Myeloma).

Cerba Research was not the Biotech's central or specialty laboratory on the study, but brought in for our expertise on the tech transfer.

Key Achievements

- Successful Tech Transfer in 4 days on-site training
- Link setup of reflex assay to corresponding reportables
- Full data interpretation workflow established (with results from other central lab)

Timeline



Challenges

Our competitor (a top 3 CRO) provided services for a client's clinical trial but had no flexibility or experience in the transfer of reflex assays. As a result, Cerba Research was brought in as a third party and expert for the transfer.

For this study on Relapsed or Refractory Multiple Myeloma (MM), an IFE Reflex Assay tech transfer was required. Unfortunately, there was no prior experience in the laboratory in China; thus, the tech transfer was implemented from scratch.

Services Provided

- Theoretical training on the assay through teleconference
- Translation of the standard operation procedures and drafting instructions for validation runs and technology transfer
- Hands-on training on IFE reflex assay, interpretation of results and reporting, and case studies
- On-site feedback on interpretation of the results of the validation done by local Chinese lab
- Creation validation report

Successes

The Cerba Research Science Team successfully completed the tech transfer through a combination of 4 days of on-site training and theoretical training through teleconference. The short and intensive training process resulted in the local staff being trained to execute the assay, operate the instruments, and do immunofixation and MM read-outs. Despite being brought in as a third party only, our flexibility ensured the establishment of a complete data interpretation workflow and monthly data transfers.