REGULATORY COMPLIANCE ASSOCIATES® INC
Wellness for Business®

Biosimilar Drug Development

Client

Mid-size

Industry

Biosimilar

Business Challenge

Client wanted to utilize the data from a recently completed Phase III clinical trial conducted entirely outside the US and not under an IND.

Project Timeline

N/A

Client Challenge

A European based company engaged in biosimilar drug development requested RCA to develop a regulatory strategy, whereby they could seek approval for their drug in the US and EU. A major challenge was that the client wanted to utilize the data from a recently completed Phase III clinical trial conducted entirely outside the US and not under an IND. RCAs regulatory affairs team, confirmed that CDERs Office of Biotechnology would have jurisdiction. After reviewing all current FDA guidance, RCA proposed that the client request an initial advisory meeting as this would be their first contact with FDA.

RCA Approach

The first hurdle to overcome was verification that clinical data met cGCP, cGMP and to FDA regulations and guidance documents pertaining to Use of Foreign Clinical Data. Since the client did not originally intend to seek FDA approval, they adhered strictly to the EMA approach which is different. RCA supported the Client as they retrieved copious amounts of records and documents. Slowly, adequate documentation was sorted from that generated, to conform to EMAs similar but different requirements. When reconstructed, this documentation essentially met FDAs requirements for cGCP.

The next hurdle was to pull together a briefing package on behalf of the client to support an Initial Advisory Meeting request. As the client was in the process of preparing a Biological License Application in Europe at the time, substantial Safety, Efficacy, Pharmacology and Bioanalytical data was available. The client had substantial bioanalytical data comparing their biosimilar to the European marketed reference listed drug “RLD”. Generation of comparative bioanalytical data that could be used to build a bridge, to the US RLD drug, was still on-going.

RCA submitted an FDA briefing package on behalf of the client. FDA rejected the meeting request based on insufficient bioanalytical comparison data between the clients biosimilar and the US RLD. Over a four- month time period the client was able to generate additional bioanalytical comparison data to the US RLD.

RCA updated the original briefing package to include additional data and resubmitted another meeting request. This time the meeting request was granted. However, due to the extensiveness of the supporting data presented in the briefing package, FDA offered the option to the client to convert the advisory meeting into a BPD type II meeting request. As a result, the client saved a significant amount of time towards their goal of filing a BLA in the US.

Results

The outcome of the meeting request with FDA is being withheld at this time to maintain confidentiality for our client.