

Case Study: Technical Due Diligence on a Biologic

The Situation

Our client is a private equity backed, small pharma company. It has a clear strategy to take on niche molecules that have a degree of difficulty, favouring value over volume. The client has extensive experience in small molecules but limited knowledge of biologics. For a large molecule opportunity in the autoimmune space, they asked Pharmagro to carry out a due diligence on the molecule Developer, focusing on CMC aspects. The molecule is developed as a biosimilar. We complemented the client's commercial managers with a senior, experienced team with technical depth and business breadth.

The Questions To Answer

Is The Cell Bank Viable & Reliable?

We analysed the development of Master Cell Bank, Research Cell Bank and the strains and vectors used. Estimated the work required to move to a GMP status and for a full characterisation for safety, identity and purity.

Are The Analytical Methods & Data Likely To Convince The Regulators?

Around 40 methods had been developed of which 10 were critical. We identified gaps in the analysis of reference product samples. Critical Quality Attributes and relevant methods were assessed. We provided guidance on how the Developer should strengthen their package.

Is The Manufacturing Process Scalable & Transferrable?

Like many small start-ups, the Developer had given little attention to the consistency of the manufacturing process, although the parameters were complex. An unusual chromatography train was identified as a potential issue. Prior knowledge of the proposed CDMOs was applied.

Does The Proposed Clinical Pathway Make Sense?

The developer had proposed a very minimal approach. Discussion on whether a PD/PK only strategy would be sufficient. We scrutinised the clinical design and patient cohort numbers.

Are The Volumes & Cost Of Goods Sold Viable?

Although our client would take only the European market, a global manufacturing strategy was required. We modelled the different volumes under scenarios of fast / slow market take up.

Do We Believe That The Management Team Can Execute On The Transfer?

Pharmagro assessed the strength of the Developer management team and capabilities to execute the Tech Transfer.

The Result

In just four weeks we provided a strong analysis of CMC elements, embedded in financial, legal and operational issues. To find out how we came to our recommendation on the path forward, and how we can serve you, contact us.