propharma

case study

ensure successful acquisitions with complete and accurate regulatory due diligence

Service Area: Regulatory Sciences – Due Diligence

ProPharma successfully supported a client with a critical biotech acquisition, conducting an extensive due diligence process to uncover business-critical risks.

When considering the acquisition of a new company or product, it is crucial to have as much relevant information as possible in order to thoroughly evaluate the potential investment. Part of this process includes knowing what questions to ask in order to uncover potential red flags that may need addressing.

ProPharma successfully delivered a due diligence report supporting the client with a description of business-critical risks, allowing them to develop and implement a strategy to mitigate the risks.

The key to successful Mergers & Acquisitions (M&A) is a specialized, rapid, effective, and thorough due diligence investigation that uncovers both critical and minor risks to best assess the value of the project. Outsourcing this exhaustive task to an expert partner will ensure timely and informed decision-making.

challenge

When you are considering the acquisition of a new product or company, you must be certain that all parts function as promised and there are no hidden issues that will be uncovered after purchase. The best way to do this is to conduct a regulatory due diligence review. In most cases, you need to complete this work quickly and efficiently by an independent third party who will ensure that important issues are not overlooked.

ProPharma worked with an investment firm that was planning to acquire a US biotech company. The company had filed a New Drug Application (NDA) with the FDA and a Marketing Authorization Application (MAA) with EMA for a solid oral dosage treatment for a rare hereditary disease. Before making a final purchase decision, the investment firm engaged us to have our team of experts analyze all available information and perform a rigorous regulatory due diligence review of the asset, with the NDA being the highest priority. The findings and recommendations would be reported back to the client, including general recommendations, go/no-go advice, regulatory hurdles, suggested next steps, etc. so the client could make an informed decision on their acquisition.

solution

ProPharma mobilized a team of consultants in the US and EU representing necessary scientific disciplines to assess the viability of approval/review issues, potential label/red flags for commercialization, supply chain paper review (Chemistry, Manufacturing, and Control approval perspective and their ability to meet commercial needs, weak links, etc.), and potential post-marketing requirements.

After meeting with the client to learn everything about the acquisition, we set up weekly teleconferences to discuss fi findings and recommend areas of research. We planned and made site visits to manufacturing plants, R&D facilities, and the company's corporate headquarters.

Our team spent several months reviewing the regulatory dossiers of the target company's pipeline and triaged our findings as:

- **Critical:** Issues likely to jeopardize eventual approvals. Critical fi findings were communicated to the client within 24 hours of discovery.
- **Major:** Issues that are likely to be noticed by the FDA and or EMA, will not jeopardize approvals, but will need to be addressed by the Sponsor and may delay the approval. Major findings were communicated to the client in weekly meetings.
- **Minor:** Issues that are likely to be noticed by regulatory authorities but will not jeopardize or delay the FDA or MAA approval. Minor fi findings were presented at the completion of the project in the fi final report.

results

ProPharma developed a clear understanding of the client's requirements and objectives, which allowed us to ensure the outcomes of the due diligence project would help the client achieve these. **Our due diligence presented risks to the client's business related to the NDA and MAA, which could potentially be complex and/or business critical. This helped our client identify the risks associated with the project, allowing them to develop and implement a strategy to mitigate these.**

During the review process, potential minor and major issues were pursued; it was important to understand the root problems and potential remediation. No critical issues were revealed during the investigation process. Not unlike a home inspection, our comments and conclusions were used by our client in their negotiations with the target company.

Our due diligence effort was completed rapidly. The acquisition was successful, and we were asked to stay on to assist with the regulatory integration.

Regulatory Expertise

Whether you are considering a major corporate pharmaceutical acquisition, or the acquisition of an asset such as a product, corporate division, or an entire company, ProPharma's regulatory due diligence review process will arm you with the appropriate information to make a well-informed decision.