CASE STUDY

Developing a Viable Regulatory Strategy Taking the Regulatory History Into Consideration

SCENARIO

A small biotech company had just acquired a new asset, a drug product that had already started phase 2 clinical studies, with phase 3 clinical trials planned toward an NDA to be submitted by the cross-functional team.

THE CHALLENGE

The business development team was familiar with the newly acquired product from a high level. The cross-functional development team, which included nonclinical, clinical, and CMC team members, was a bit unclear about the regulatory pathway options.

THE STRATEGY

A review of the development history began with a gap analysis of all the pre-IND and IND submission components. The gap analysis reviewed the formal and informal communication paths between the previous company and the FDA, including all the email correspondence between the regulatory point person and the FDA project manager.

The communication history provided vital information on the previous regulatory program and uncovered potential nonclinical, clinical, and CMC scientific options. This helped set the direction of the next steps within the development plan of the product.

A review of the competitive landscape gave insight into the submission strategy and additional options toward the NDA submission strategy.

THE RESULT? Streamlined Regulatory Path

The outcome was a more streamlined regulatory path including transparent and clear communication with the FDA, leading to an overall better solution for the client and a shorter timeline to the NDA submission.

Regulatory Expertise

Our team of expert consultants are here to help you, leveraging our knowledge for your solutions.

Our tailored services range from ad hoc consulting, to providing a virtual C suite (CEO, CFO, CMO, CSO) clinical and regulatory team ready and able to integrate with yours.

By employing a comprehensive and customizable multidisciplinary, problem-solving methodology, we are able to reduce risks and streamline development plans.

The regulatory landscape is tough to navigate---don't go it alone.

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