CASE STUDY

Regulatory guidance and IND filing

SITUATION

A bioscience firm's complex molecule meant to target a rare disease cohort was ready to take to clinic – at the same moment the firm lost its regulatory lead. An experienced and professional scientific team was in place to move the molecule forward to trials, but expert regulatory assistance was needed to prepare the Investigational New Drug Application (IND), file the IND, and guide the firm through the FDA's IND review process.

SOLUTION

The Pearl Pathways team had an established connection with the bioscience firm's leadership. Having collaborated on previous projects, the CEO and Chief Scientific Officer knew they could rely on Pearl Pathways to pick up the reins where their regulatory lead had left off, and identify any gaps or inconsistencies to ensure a successful IND filing.

Pearl Pathways adopted a hands-on approach to assist the firm in preparing the filing. Pearl orchestrated the collection of data into a seamless storyline that FDA regulators could follow and understand. Pearl organized clinical and non-clinical data and reviewed volumes of documentation to draft development reports necessary for the submission. The Pearl team also helped the bioscience firm assemble the reports, validate the findings, and quality check all documentation. Finally, the Pearl team executed the submission through the IND gateway and triaged follow-up conversations with the FDA.

RESULT

Due to the strength of their IND filing, within 30 days of submission the firm was approved to begin clinical trials. Furthering their partnership with Pearl Pathways paid off for the bioscience firm, as Pearl's attention to detail, understanding of what's required for successful submissions, and proactive, end-to-end oversight of the complete IND filing process expedited the molecule's path to clinic—moving it closer to saving lives.

Pearl Pathways™

Pearl Pathways is a comprehensive life science product development services company. Every day we strive to provide our customers top quality service, unyielding ethics, and efficient services through our team of experts. Pearl Pathways supports biopharmaceutical, medical device, and diagnostic companies as well as life science service providers with clinical, regulatory, and quality compliance needs. Our full-service central IRB supports all aspects of human research.

Clinical: Pearl Pathways' expertise in medical practice, science, ethics, and clinical research supports all phases of clinical development. Our expert consultants help implement customized solutions that drive efficient clinical research programs.

Regulatory (drug): Our consultants draw on over 20 years of scientific, industry, and FDA experience to translate your data into strategic drug development pathways, providing guidance from molecule to market while navigating a complex regulatory environment.

Regulatory (device): Delivering superior end-to-end product development and commercialization strategies, our consultants provide regulatory guidance that adds decades of industry and FDA regulatory expertise to your team, helping you balance risk, cost, and time to market.

Quality: From risk-based quality system development to gap analysis and remediation, our partnership helps reduce operational burdens, manufacturing impacts, regulatory agency warnings, and costly recalls—allowing you to focus on ongoing product quality assurance.

IRB: Our accredited independent review board ensures quality research, unyielding ethics, and human subject protection with individualized Expedited and Full Board reviews.

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