CASE STUDY

Regulatory Strategy Consulting

Client: Mid-tier pharmaceutical company

SITUATION

A mid-tier pharmaceutical company approached Pearl for help in preparing an IND for a biologic product and providing consultation on phase 4 post approval supplements.

SOLUTION

The company had not prepared an IND for a biologic before, so Pearl's experts reviewed the first draft of the IND for a . The team reviewed the IND and identified gaps in content and format to FDA expectations. Staff rearranged the data so it was included in the appropriate sections for FDA, and reviewed drafts to ensure consistency throughout the document. Further, Pearl reviewed the data to ensure it supported the proposed studies.

For a second project, Pearl reviewed a product involving a complex formulation involving microspheres for extended release. Pearl reviewed the proposed changes and helped the client establish reporting criteria and organize the sequence of changes to minimize the risk. Ultimately, Pearl shared a plan to allow their client to make all post approval changes within one year and also meet FDA reporting criteria.

RESULT

The client valued the expert and experienced opinion that the Pearl provided for the IND. The first project led to an IND being filed, and it is currently waiting for the FDA review. For the 2nd project, the client used the plan Pearl created and is thrilled with the reduced reporting requirements. They will continue to monitor the drug supply change to ensure their supply is high quality and adequate. The client will remain to utilize Pearl for ongoing regulatory strategy guidance and consulting.

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.

29 E McCarty Street, Suite 100
Indianapolis, IN

317.899.9341 ph
317.602.6554 fax

www.pearlpathways.com
www.pearlirb.com