CASE STUDY

Clinical Research & Quality Compliance

Client: Small Pharmaceutical Company

SITUATION

A founder of a small Oncology company approached Pearl with a need for Investigatory New Drug (IND) filing support. The ultimate scope of services included oversight of manufacture of the clinical research materials, vendor assessments, quality system creation, authoring the IND, and leading FDA interactions for a pre-IND meeting.

SOLUTION

Pearl provided a team of experts to support small molecule product development. Advisors with regulatory, quality compliance, manufacturing, and supply chain experience provided support as needed to create and manage the best regulatory and CMC strategies for the client. A senior advisor worked closely with the management team to create and drive the CMC strategy for the clinical supply chain. Pearl worked closely with the development scientists to ensure product would be available for toxicology studies and clinical use. Multiple regulatory issues were identified and addressed to ensure FDA would allow clinical studies to start.

RESULT

The Pre-IND meeting with the FDA is on track by end of year 2012. Pearl has been instrumental in all preparations for the meeting and has also been slowly building an appropriate quality system for this start-up as they grow and proceed along their product development path. Finally, Pearl's manufacturing and CMC expertise have been critical in selecting contract manufacturing providers that will provide formulation development and material for use in clinical studies.

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