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™

Company Overview

Pearl Pathways is obsessed with accelerating life science product development for our clients. We are an extension of our clients' teams, partnering with the clinical team, in-house regulatory experts, the quality compliance specialists, the quality auditors, and the senior leadership team to get life-saving diagnostics and therapeutics on the market sooner. Our talented staff is focused on getting critical research done, ensuring high quality and efficient manufacturing of products, accelerating global product registrations, and keeping our clients up to date on current regulatory and quality compliance best practices for life science product development.

Pearl IRB: Protecting human subjects and driving improved value and efficiency in protocol reviews and study implementation

Pearl ReGXP: Providing regulatory & quality consulting, and auditing services

Pearl IDEAS: Offering strategic product development assistance through our life science consulting practice

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