Regulatory filing services, medical writing and study monitoring

Client: PAI Readiness Quality Compliance Services

Situation:

A small therapeutics firm with a limited quality assurance staff sought out Pearl Pathways to help them with pre-approval inspection (PAI) of their facility. The company had recently submitted a new drug application (NDA) and they knew they needed to help prepare their contract manufacturer (CMO) for the upcoming FDA inspection. Additionally, the client had at issue the fact that the manufacturing facility had not been built yet.

Solution:

Pearl Pathways sent a team of two quality compliance specialists to visit and conduct mock audits, prepare the company for potential questions, equipped them with answers, and created a strategy to address FDA questions. During the sixth month project the Pathways team visited the site twice to prepare the CMO for site inspection readiness.

Result:

The result for the client was a successful PAI. This allowed the company to proceed with the NDA approval process and deterred any delays due to CMO facility build out.

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

29 East McCarty Street
Suite 100
Indianapolis, IN 46225

317.899.9341 ph
317.602.6554 fax

www.pearlpathways.com

www.pearlirb.com