CASE STUDY

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™

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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