CASE STUDY

Regulatory, Quality Compliance, and CMC Analytical Services

Client: Small Pharmaceutical Drug Company

SITUATION

A small pharmaceutical company was preparing for a 505(b)(2) submission for a drug with a novel delivery device. The client approached Pearl Pathways to provide general quality compliance services, pivotal clinical trial support, a regulatory strategy, and filing support.

SOLUTION

Pearl Pathways' staff has been able to provide a wide variety of support for this client. Pearl's first engagement was to troubleshoot a problem at an investigator site. Pearl led a root cause analysis from the site to the manufacturing facility. Within a few months the client had expanded their use of Pearl staff to include general Chemistry, Manufacturing, Control (CMC) support, analytical chemistry consulting services, and statistical analysis to support their CMC regulatory New Drug Application (NDA) submission. Pearl worked extensively with the client's contract manufacturer to insure they were providing high quality product and data. Ongoing clinical support continued with Pearl providing a clinical trial monitor talent to assist in a separate site project.

RESULT

Client is on track to file their NDA in Q2 2012 and has shared feedback that the breadth and quality of Pearls services have been excellent. Client feedback is best illustrated in this quote "We value the breadth of Pearl's services. We can tap into their expertise for clinical, manufacturing, regulatory and quality, all in one team. For a smaller company such as ours, working with one company rather than three or four allows us to save time and trouble". Pearl's team has been instrumental in providing strategic input, content, key analyses and data, and quality oversight of the submission documents.

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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