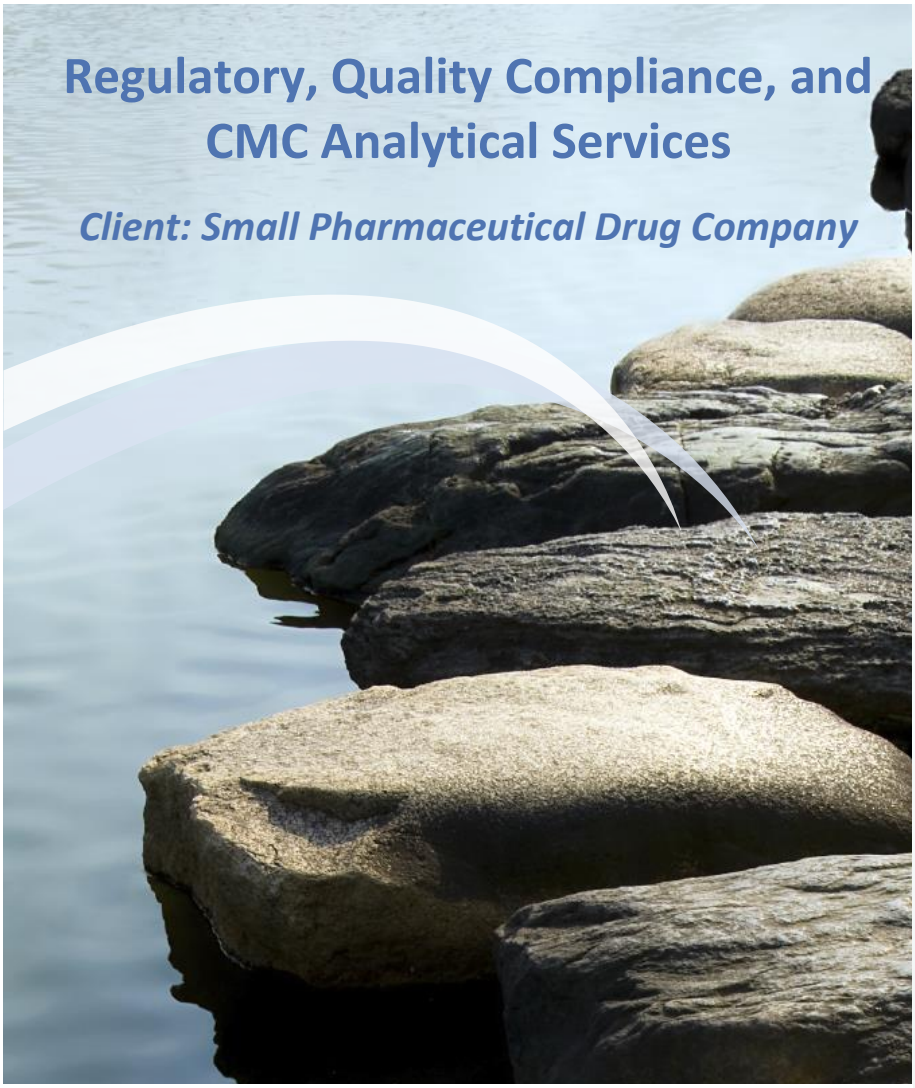
Regulatory, Quality Compliance, and CMC Analytical Services

Client: Small Pharmaceutical Drug Company



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

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.

29 East McCarty Street
Suite 100
Indianapolis, IN 46225

317.899.9341 ph
317.602.6554 fax

www.pearlpathways.com

www.pearlirb.com