Regulatory filing services, medical writing and study monitoring

Client: Large Pharmaceutical Company

Situation:

A global top five pharmaceutical company sought the services of Pearl Pathways for CMC regulatory support. The pharmaceutical company had recently reduced its workforce in anticipation or some organization changes which did not occur. A senior leader at the pharmaceutical company reached out to Pearl to fill this gap in regulatory support.

Solution:

The scope of the project was providing ongoing global CMC regulatory submission document authoring for both new and existing biologic products. Regulatory submissions included INDs, IMPDs, marketing authorization applications, annual reports, and other ongoing changes.

Pearl Pathways provided three regulatory advisors with quality CMC experience to improve organization of filings, and author needed documents. Pearl Pathways has shown flexibility on a recent submission due to the creation of new IMPDs in parallel with a changing formulation of a drug dosage. Pearl staff has also effectively managed health authority questions on behalf of their client.

Result:

Pearl staff was able to learn new IT systems, forms, and the processes of their large client quickly. They have been able to navigate and master their processes and learn their biologic product line. One example of results to date includes meeting the deadline for a large IMPD involving every module. Overall, over six annual reports, IMPDs, marketing authorization applications, and other regulatory submissions have been supported in 9 months. Pearl Pathways provides high quality ongoing support for this client and continues to grow in volume of projects and complexity of support.

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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