CASE STUDY

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™

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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