CASE STUDY

Medical/Scientific Writing

Client: Biopharma Startup Client

SITUATION

A startup biopharmaceutical company asked Pearl for assistance in preparing scientific reports and manuscripts for regulatory submission, and in support of an upcoming product approval and launch. The client also required help composing several pharmacokinetics publications, abstracts, and posters.

SOLUTION

Pearl provided a team of medical writers, biostatisticians, and clinical and scientific experts to work collaboratively with the client. Pearl led all medical writing activities and a cross-functional team to manage the project, including efforts to secure references and raw data. At the project's conclusion, Pearl helped the company produce a total of 16 high-quality, submission and publication-ready reports and manuscripts.

RESULT

The client met their project deadlines early, received regulatory approval, and successfully published in peer-reviewed journals. They were extremely pleased with the quality of the writing and has worked with Pearl on many subsequent projects.

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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