PharmaWrite®

Delivering CSRs Through Partnership with PharmaWrite

An example of how a productive collaboration with PharmaWrite can help your company deliver more impactful, accurate, data-driven clinical study reports (CSRs).

The importance of collaboration

Overview

A small biotech company located on the West Coast recently reached out to PharmaWrite to provide **medical regulatory writing services** in support of their portfolio development. Specifically, the company sought assistance in the medical writing of clinical study reports (CSRs) for two Phase I studies that were needed as part of a comprehensive submission strategy.

Utilizing a structured sequence of project management steps and support, and through productive collaboration, **PharmaWrite produced quality final versions of the CSRs on time and on budget**.

After this successful collaboration, the satisfied company has continued to work with PharmaWrite. Since that first partnership, they have made additional requests for CSRs as well as an expansion into another vital area – the organization, writing, and finalization of new standard operating procedures (SOPs) for CSR writing.

Proven methods

Project Summary

PharmaWrite's initial task was to provide medical writers and project leaders who would be able to **successfully collaborate with the client's team** to review the clinical data, align with the client's template, and to meticulously prepare the CSRs as final, submission-ready documents.

To achieve this, PharmaWrite **identified a project lead** with significant regulatory documentation experience to lead the writing team of senior writers and editors.

As the project progressed smoothly, the client **increased the scope of the effort** by requesting that PharmaWrite additionally take on the creation of appendices. This supplementary task of preparing the appendices for the reports was easily incorporated into the PharmaWrite project plan and successfully completed by the writers and editors.

PharmaWrite's proactive approach included significant project planning, bi-weekly meetings to review and assess progress, and the creation and implementation of a detailed style guide that provided the foundation for all reports.

These proven methods helped PharmaWrite to complete the project on time and with high quality – and resulted in extremely positive post-project feedback from client team members and executives alike. It also resulted in a new and productive business relationship.

Your solution

PharmaWrite is at your service to customize and deliver effective and comprehensive regulatory writing services to match your needs and achieve your business objectives – all while upholding the highest industry standards.

To learn more, please visit the PharmaWrite website. Or, for additional inquiries and information, please reach out directly to:

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