Case Study:
Successful US/EU Marketing Applications for Big Pharma

INTRODUCTION:

As a result of repeat business, IMPACT (now part of Syner-G BioPharma Group) was contracted by a large, global pharmaceutical company to author the CSRs and accompanying submission documents to support a simultaneous US and EU submission for a combination respiratory product.

THE PROJECT

This work included authoring 9 CSRs (8 Phase 3 and 1 Phase 2b) as well as the Integrated Summaries of Efficacy and Safety (ISE and ISS), Summaries of Clinical Efficacy and Safety (Modules 2.7.3 and 2.7.4), Summaries of Biopharmaceutic Studies and Clinical Pharmacology (Modules 2.7.1 and 2.7.2), and the Clinical Overview (Module 2.5).

Initially, the project was managed by the client, but due to resource constraints, project management responsibilities for the NDA and CSRs were transferred to IMPACT's internal project manager early during the submission process. Over the course of 12 months, IMPACT's Project Manager worked closely with the client and IMPACT staff to ensure consistency of messaging across the CSRs and submission documents.

Nine IMPACT employees were involved with authoring, quality control, and document management of this submission. All documents produced were of the highest quality and in submission-ready format, and both marketing applications were submitted to the US and EU regulatory agencies according to the client's timelines.

Meanwhile, during regulatory review of the marketing applications, IMPACT authored 3 Phase 3b CSRs for head-to-head comparator studies in support of product launch. The combination product was approved in both the US and the EU. Upon the successful conclusion of these submissions, IMPACT has received additional submission work from this client and has recently been selected as a preferred provider.

This project epitomized IMPACT's model of becoming an extension of a client's project team. All team members worked closely together towards the mutual goal of application submission and product approval. This success would not have been possible without the focused and knowledgeable guidance of the client's Project Leader and IMPACT's Project Manager, who worked hand-in-hand to get this product to market. Our excellent relationship with this client continues to this day.

ABOUT US

Syner-G BioPharma Group provides in-depth expertise across the three key elements of Chemistry, Manufacturing, and Controls (CMC): Regulatory Services, Technical Development, and Quality/IT. We call this CMC 360™. We also provide medical writing services, with expertise in authoring a variety of regulatory documents across a wide range of therapeutic areas and in all phases of development. Our regulatory affairs services include the development and implementation of global regulatory strategic plans, regulatory agency meeting support, and electronic submissions to regulatory authorities around the world.

We have the skill set and experience to guide your prime asset through any development challenges and along the ever-changing maze of regulatory filing pathways, to a position of full compliance, and high quality. Our expertise spans small molecules, peptides, oligonucleotides, biologics, monoclonal antibodies, antibody-drug conjugates, and cell and gene therapy products.

Ready to learn more about how Syner-G can support your organization?

Contact Frank Sorce, Senior Director, Business Development
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Syner-G's Mission: Enable our clients to achieve success and enhance human health through the efficient development of new therapeutic agents while inspiring our team members to excel.