Case Study:
Expert Regulatory Affairs Services for a European-Based Client

INTRODUCTION:

Following referral from another company, IMPACT (now part of Syner-G BioPharma Group) was contacted by a small development stage pharmaceutical company located in the United Kingdom to assist them with pre-IND activities for a new chemical entity for the treatment of asthma.

THE PROJECT

To assist the client with US development of their product, IMPACT brought together a virtual project team consisting of a group of regulatory, clinical, nonclinical, and CMC experts to provide strategic input and guidance on the appropriate development path in the US.

During the pre-IND stage, IMPACT:

- Requested the Pre-IND Meeting with the FDA
- Provided valuable strategic insight into the appropriate questions and regulatory issues that were discussed with the Agency
- Authored the client's Pre-IND Briefing Document
- Assisted the client with all preparation activities for the Pre-IND Meeting (e.g., rehearsals for the meeting, brainstorming on questions that have been raised by the Agency)
- Attended the Pre-IND Meeting as the client's regulatory representative
- Prepared the client's internal meeting minutes for submission to the Agency
- Helped to clarify some discrepancies between the client's understanding of the agreements during the meeting and the Agency's formal meeting minutes
- Worked with the Agency to ensure that documentation was prepared clarifying certain issues for the record, to the satisfaction of the client

Following the successful Pre-IND Meeting, IMPACT was asked to prepare and submit the client's IND. IMPACT authored the clinical, nonclinical, and CMC sections of the IND and also compiled the full paper submission (in CTD format). The IND was submitted in accordance with the client's timelines and was accepted by the appropriate FDA reviewing division.

During the review period, the Agency raised several challenging questions with regard to some nonclinical findings. IMPACT worked closely with the client to determine the appropriate strategy for responding to these questions and aided in compilation of the responses on a very tight timeline. The responses were accepted by the Agency and the IND was cleared within the 30-day window.

Following successful clearance of the IND, IMPACT was asked to provide IND maintenance for all subsequent activities under the IND. IMPACT has continued to serve as the client's Authorized US Representative with the FDA over the past 2 years.

IMPACT's involvement in the very early stages with this product allowed us to establish trust with this client, and they came to rely on us for our regulatory expertise and guidance. Through our team of experts, we were able to provide valuable strategic and regulatory insights that resulted in a successful Pre-IND Meeting and, in turn, important Agency feedback on the client's development plan. In addition, IMPACT's dedication to the client in preparing a thorough and comprehensive IND of the highest quality resulted in a successful IND filing. Ultimately, our regulatory and strategic guidance helped them navigate the potential roadblocks and resulted in a clear and active IND with no clinical hold issues.

THE CLIENT'S PERSPECTIVE

"IMPACT has demonstrated a vast knowledge of the US regulatory environment and this, combined with their positive "can-do" attitude and friendly approach ensured our IND plans were achieved in the timeframe we wanted. We have been extremely happy with the experience, capability and service they brought to our company's first regulatory procedure in the USA. We look forward to our continued relationship working together in the future and we would not hesitate to recommend IMPACT."

– Client's Director of Regulatory Affairs and Product Development

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.