

# Navigating Critical Regulatory Requirements in Alignment with Sponsors' Unique Challenges and Goals

Careful, timely, and strategic navigation of regulatory requirements is essential for sponsors who hope to achieve commercial success in the United States. The FDA provides a broad spectrum of regulations and guidances to assist sponsors, and at first glance it might appear that these can make the process straightforward and manageable. The reality, however, is usually different.

Employing the guidances correctly, knowing which are appropriate for what therapeutic area, and applying them at the correct time in the development process can be quite challenging. In addition, new guidances are issued by FDA and other global health authorities on a daily basis. A further complication is the fact that the guidances are open to interpretation. Experience with current programs, the regulatory competitive landscape, development trends, and the successes and challenges that others have met in the recent past is vital.

The TBG team understands exactly how the relevant guidance pertains to a particular development program or product from a particular sponsor in a particular moment. That expertise is essential to any sponsor who intends to succeed.

## The Challenge for TBG

The first step for us at TBG is to help the client understand the nuances of their situation and the different approaches available to them based on their tolerance for risk. Unfortunately, the path forward is not always straightforward and the process can be an iterative one.

## A Case in Detail

Recently, a sponsor approached TBG as part of their quest to move forward with the COVID-19 Emergency Use Authorization (EUA) process. The sponsor asked TBG to fill out a few forms for them. As the TBG team examined the information provided, it became clear that one of the forms at hand was not the right one. In fact, the “right one” did not exist. As an alternative, TBG suggested the sponsor supply a Reviewer's Guide to more fully explain to the FDA their data package and their desired path forward.

The FDA appreciated receiving this more comprehensive document in addition to the standard form. But, shortly after the Reviewer's Guide and form were submitted, the FDA issued a new form, which necessitated a new submission. While this development was somewhat frustrating for all concerned, having the Reviewer's Guide available allowed TBG and the sponsor to resubmit in record time.

## The TBG Solution

The development of products for COVID-19 was complicated at the time by the fact that understanding of SARS-Cov-2 was steadily evolving, necessitating frequent updates and changes from FDA.

In situations like this, TBG is able to leverage extensive prior experience with FDA to predict changes that are likely as a result of the changing landscape. With this in mind, TBG collaborates with clients to develop a sound strategy that can withstand change. When changes do occur, we are prepared with the information necessary to satisfy FDA's updated requirements.

## TBG Services and Deliverables:

Regulatory services and deliverables vary greatly from client to client depending on the specific needs and interests. Some clients prefer just intermittent input from TBG and continue preparing their strategy and documents with the aid of periodic TBG/sponsor touchpoints. Other clients prefer more interaction and collaboration and a team approach. Still others engage TBG to handle almost all the regulatory and strategic input and content submissions. These sponsors simply review key documents to ensure the path forward is the one they envisioned. We at TBG are happy to customize each engagement to suit each client's goals and needs.

## The Results

No matter at what phase of development a client engages with us, we at TBG are always pleased to help the client in their journey toward solving their unique development and regulatory challenges, helping to direct and/or redirect the course, and positioning them for success.

## The Takeaway

Success with regulatory requirements is at times process driven while at other times, strategic decision making is essential. In either case, nothing else happens if regulatory requirements aren't met. Sponsors who want to be sure of success can rely on the team at TBG to get them there.

