BRACKEN

Providing Agile Regulatory Expertise

for Teams Temporarily Under Resourced

Finding, securing, and retaining the top talent required to be an integral part of drug development programs through Health Authority, i.e. FDA, approval is no small task, and the costs associated can be significant. Companies should know that there is an alternative path to pursue in securing critical expertise, especially when time is of the essence. Taking advantage of services like those offered by Bracken is not only exceptionally flexible and cost effective, it can also minimize gaps in the in-house regulatory support.

The Challenge

Successfully providing critical and short-term services to life science companies requires a unique set of talents in the temporary team members. They must be highly knowledgeable and experienced in order to hit the ground running in the most challenging circumstances. Yet, they must also be willing and able to join an existing team seamlessly, without creating any unnecessary disruption. Finally, they need to understand both when to step up and when to step back.

A Case in Detail

A biotech engaging in innovative work in oncology was short-handed in its regulatory department and in need of assistance with managing multiple open Investigational New Drug (IND) Applications, as well as organizing its vast, historical project files. Bracken was originally contracted to serve as an interim head of regulatory and provide the services of a second, supporting regulatory professional. Ultimately, all members of the client's regulatory team left and the two Bracken regulatory professionals became the entire regulatory department for a company with numerous ongoing drug development projects.

And The Bracken Solution

The Bracken team members were asked to increase their hours and extend the term of their commitment to meet the expanded needs of the biotech company so that regulatory operations could proceed without a misstep. Along the way, Bracken provided its client with complete confidence that regulatory affairs were in good hands, both from the strategic perspective and the day-to-day execution and submission activities. The Bracken team was able to integrate seamlessly with the existing in-house team.

"They knew that we were getting things done and felt comfortable being involved or not involved as they wished," said a Bracken team member.

When the company's new, permanent head of regulatory took up her post, she was delighted to find everything in good order and relied on the Bracken consultants to assist with bringing her up to speed on ongoing projects. The Bracken Team has remained part of the extended regulatory team available on an ad hoc basis.

Bracken Services and Deliverables

- Several months of expert, executive level regulatory leadership via Bracken's Virtual C-suite services.
- Day-to-day support of regulatory operations via an interim regulatory professional.
- The Bracken Regulatory Team is part of the extended regulatory team for several clients and provides ongoing embedded and ad hoc services.

The Takeaway

Companies that need time-sensitive and project-critical assistance, whether it is strategic or routine submissions, can trust Bracken to deliver an efficient, effective, fiscally responsible solution that will support success for as long as that support is needed, and graciously hand over the reins when the need for support has ended. Bracken can remain available on an ad hoc basis, just in case support is needed from time to time, and is just a "phone call away."

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