Regulatory and Quality

PUTTING THE PIECES IN PLACE TO SUPPORT IND SUBMISSIONS—AND AN IPO

Drug discovery, development, and commercialization is like a puzzle. The end may be easy to visualize, but there are many pieces that need to be in the correct place for it all to come together. Those pieces include successful clinical trials, agency approvals, and development funding. But they also might include consistent documentation, knowledge-sharing tools, and clear cross-functional communications.

It's challenging for any new pharmaceutical, biologic, or gene therapy development team to get the right pieces in place at the right time. But for a startup company, which typically has fewer resources and new organizational dynamics, the challenge is even greater.

WHEN PLANS ARE BIGGER THAN CAPABILITIES

Such was the case with a new company with aggressive plans to develop two therapies a year for the next few years. It was working to gain Investigational New Drug (IND) approval on the first two. The overlapping timelines were tight and drugs' different modalities required different cross-functional support, regulatory documents, and language.

The company planned an IPO and needed to show both progress and potential to win investor confidence. However, as it implemented new finance and procurement processes and enterprise systems, the company stretched its limited staff even more.

A few of the employees had experience with INDs and helped provide guidance, but resources were thin. Teams of innovative scientists were doing good work, but the company had no formal timelines, centralized communications, or clear decision-making. Teams that did interact had version-control problems because they stored information in multiple locations. Decisions made in meetings weren't consistently recorded or reported. Everybody said the timeline and milestones were unrealistic, but nobody was accountable for them. Were they really unrealistic or simply ignored?

ORGANIZING ALL THE PIECES

The company brought in Integrated Project Management Company, Inc. (IPM) to develop and lead the IND submission process. The two products' different modalities meant different pathways. With IPM's strong background in both drug development and program management, the consultant was able to hit the ground running. She worked with team leads in the regulatory, pre-clinical, CMC, and other departments to create a roadmap. It included both timelines, integrated to show interdependencies, specific responsibilities, and functional handoffs. The consultant applied her experience to study the content and timelines, recognize where problems might occur, and ask challenging questions. She was also able to help remove roadblocks and identify solutions when necessary.

To increase transparency and improve communication, it was important to bring the functional teams together. They established a tool to centralize information. Changes and updates were discussed and agreed to before they were made. The tool not only served as a single source of truth, but it also helped to build accountability because everyone could see what they were responsible for and how it impacted others and the timeline. Having information in one place also made it easier to prepare FDA communications and answer questions from the agency.

Importantly, IPM's consultant structured communication to move up the ladder. The team was able to provide manageable expectations to executive management, who gained confidence in the company's ability to meet milestones. The streamlined communication also supported the management team and executives' efforts to get the company in shape for IPO.

MORE TO COME

Each therapeutic received IND approval and is now on its way to clinical trials. Having documented processes and predictable filing milestones for IND submissions—as well as transparent, cross-functional communications—continues to help development.

Consistent processes and communications also helped the company's IPO effort; it went public prior to the IND approvals. Ultimately, the company continues to carry out its plans for two IND filings per year.