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WHITE PAPER

The Cornerstone of Virtual/Outsourced Drug Development: CMC Project Management

Drug development is a highly complex task that is a scientific, data-driven, multi-disciplinary and detail-oriented activity. It requires diligent and proactive planning and management to overcome many significant obstacles in the path of success. In the pharmaceutical industry, CMC (Chemistry, Manufacturing, and Controls) is a critical function in the successful development and commercialization of new drugs.

In the pharmaceutical industry as a whole and, especially, start-up biotech companies, the reliance on a virtual drug development model that involves global outsourcing of CMC activities has greatly increased. As a result, proper and proactive management of the drug-development project is extremely important to ensure the success of the project measured by timely completion within budget and meeting regulatory expectations of quality and compliance.

Within CMC, the project management function is the central point that connects all the moving parts in the CMC operations such as the CDMOs, scientists, and management to ensure that the virtual drug development CMC operations are coordinated and aligned to achieve the desired corporate goals. This is achieved by developing a detailed CMC drug development project plan with input from all stakeholders including CDMOs. The plan should detail the budget and key milestones. Establish a communication plan including routine and timely meetings, clear metrics for continuous tracking of activities and deliverables against the agreed project plan, and monitoring against the budget. The project manager, to achieve their task must relentlessly follow up with all stakeholders and clearly communicate the project status with the cross-functional project teams and management.

Based on Syner-G's experience in managing hundreds of INDs and NDAs, we see two schools of thought among startup companies; one that recognizes the importance of the function of project management with an effective project manager and implements this role with defined responsibilities early on in the drug development plan; and the other that believes in "outsource and forget" model, relying fully on the CDMOs to manage and execute the activities in the sponsors' best interests. The second approach is very appealing because of the perceived cost savings and the misconception that the CDMO knows how to manage the project for the client. The value of active project management by the client is intangible in the short-term but in the mid-term to long run, the cost of having a project manager will pay for it in multiples by the timely and successful completion of tasks, progression of the projects, and meeting corporate goals. It is a myth that one can simply outsource CMC activities and expect that results will be delivered on time, on budget, and to the expected standards of a management team.

There are two main reasons why active project management by the client (or their designee) is very effective. The first one is that the output results are directly proportional to what you manage; in other words, you don't get what you ask or want but what you manage. Because of the multitude of moving parts including geographical locations, priorities, scattered and inefficient communications, etc., it is critical to have an internal champion to drive the overall outcome of the project. Secondly, the output results are again directly proportional to the awareness of strategy and closely monitoring the progression of a project. The CMC project manager from the CMDO is usually remote, hence devoid of critical information such as the client's priorities, corporate strategy, and goals. Added to this are the cultural, leadership, and communication differences which make the PM activities by the CDMO ineffective. Therefore, the more deliberate a sponsor is with assigning their own project manager, the more predictable arethe outcomes.

Pharmaceutical professionals who have a good mix of scientific knowledge including drug development lifecycle, regulatory, quality and compliance, and leadership skills such as leading without authority are ideal successful CMC project managers. Successful CMC project managers generally have a few years of hands-on CMC development experience, understand the concepts of pharmaceutical development related to drug substance, drug product, and analytical chemistry and the interplay between these functional areas and the overall drug development (including clinical and toxicology functions). They also have the basic understandings of quality, compliance, and regulations, and appreciate the challenges associated with the global CDMO model (geographical, cultural, communication, language, leadership, etc.) to anticipate, plan and mitigate the potential pitfalls of the outsourced working model. They are comfortable in learning and adopting project management tools such as MS Project to track the project activities and continuously monitor and communicate the progress of the project. They have good organization and time management skills and are good with written and verbal communications.

Conclusion

In conclusion, the project management function within CMC is extremely important to ensure the success of the virtual drug development for CMC operations. By utilizing a project manager and project management systems, projects are better organized and the deliverables are tracked consistently across and between departments. Project managers keep key personnel and stakeholders informed and engaged, ensuring that project work progresses in a timely, effective, and orderly manner, and significantly increases the likelihood that a project will be successful. Simply put, project managers add value by improving project performance.

ABOUT

Syner-G

Syner-G is the premier solution provider of Chemistry, Manufacturing, and Controls (CMC) services for the life sciences industry. The company's approach is based on CMC 360™, a fully integrated suite of CMC solutions that encompasses pharmaceutical development, regulatory affairs, and quality/cGxP compliance. The entire Syner-G organization is built around the premise of guiding small molecule, biologics, cell and gene therapy, and medical device innovators through the CMC process.

Since its founding in 2007, Syner-G has enabled clients in their quest to bring life-saving and life-enhancing products to patients. Today, the company has grown to more than 100 employees globally, been recognized as one of the "Top 10 Drug Development and Consulting Services Companies" by Pharma Tech Outlook, and served as an integral part of more than 500 various types of successful regulatory filings. For customers looking for offshore resources, Syner-G also offers CMC services based in India.

Syner-G's operations in India follow the same CMC 360™ model used in the U.S., further differentiating the company from typical CMC consultants.

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