Halloran

A ProductLifeGroup Company

Case Study:
Turning Drug Development Chaos Into Order For An NDA

Situation:

The average approval time often takes 10-15 years from Phase 1 to approval.[1] The cost of drug development for sponsors ranges from $314 million to $2.8 billion.[2] The milestone of submitting a New Drug Application (NDA) for approval by the U.S. Food and Drug Administration (FDA) is typically a high priority.

Considering the time and cost considerations, a small biopharmaceutical company with a targeted oncology pipeline approached Halloran Consulting Group (Halloran) requesting Development Program Management with regulatory expertise to assist with their first NDA filing to the FDA.

Challenge:

The company received multiple regulatory designations (orphan, fast track, breakthrough designation, priority review and real-time oncology review) to accelerate their approval pathway. However, they lost their Development Program Manager, recently hired a Senior Vice President of Regulatory Affairs, and their internal development team was not fluent in NDA submissions.

As a result, the company had timelines that were not adequately managed, incorporated new resources that changed internal dynamics, and did not have a catalyst to propel development towards the NDA.As a result, the company had timelines that were not adequately managed, incorporated new resources that changed internal dynamics, and did not have a catalyst to propel development towards the NDA.

Solution:

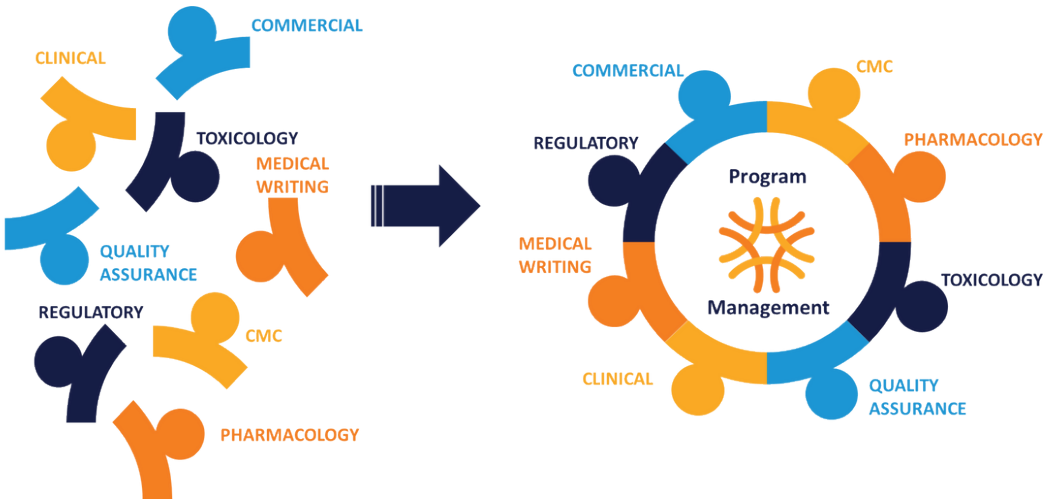
Halloran engaged the company by addressing their key internal infrastructure gaps relating to communication, governance, process, resources, tactical strategy, and timelines.

Halloran put the following infrastructure in place:

- Proactive strategic planning to minimize risk
- Established governance to communicate concerns effectively
- Created timelines to hold team members accountable
- Developed progress reports to consistently communicate status
- Planned resources to ensure people were available to help
- Invested in lessons learned to share and continuously improve

Results:

The company evolved from a fragmented organization to an integrated unit propelled by proper planning, communication, collaboration, and high performance. This new framework enabled the team to successfully submit their first NDA to the FDA.



Program Management at Halloran

Halloran's Program Managers define the strategy within their clients' cross-functional teams and lead the development program through execution. Halloran's interim Program Managers offer their clients a competitive advantage through their integrated insights and learnings from the development of similar types of products in the industry.

About Halloran

Halloran experts offer deep expertise in science and advanced knowledge of the development and commercialization lifecycle, leading clients through their most challenging business goals to achieve their greatest chance of success. Whether it is leading new company formation with a fully integrated development team at the ready, enabling investments with robust diligence or market assessments, or providing accelerated, durable development strategies for enhanced company value creation, Halloran is your development partner.

Ready to get to work?
Contact us

Cited Sources

[1] PhRMA. 'Biopharmaceutical Research and Development: The Process Behind New Medicines'.
[2] Terry, M. 'The Median Drug Development Cost is $985 Million, According to New Study.' Biospace, 2020.

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