

Case Study: Regulatory Portfolio Management: From Bad To Gold



Situation:

To support the complexity of product development and regulatory submissions, proper management is required to support pipeline growth and oversee timely regulatory activities.

A small immuno-oncology biotechnology company was in a similar dynamic and engaged Halloran Consulting Group (Halloran) to request a Regulatory Program Manager to manage their regulatory portfolio. The company had over 20 programs in various stages of development and needed to quickly gain visibility and oversight on all programs.

Challenge:

Since the company's pipeline had assets in various stages of development, diverse plans for each asset, multiple silos of information holders, and high personnel turnover rates, there was a need to have a more holistic view and oversight of all the programs. Though this company had an early-stage program management infrastructure in place, they needed a program manager with deep regulatory experience to create regulatory affairs continuity throughout their pipeline.

The company also needed a clear path to understand the history, strategy, and real-time status of each program within their portfolio to fulfill internal timelines and deliverables, communicate information across multiple internal teams, and prepare for future U.S. Food and Drug Administration (FDA) interactions.

Solution:

Halloran engaged the company by addressing the organizational problems in a multi-phased approach:

Assessed Gaps

Reviewed how tasks were accomplished, assessed who held critical information, and determined if a useful background package existed

Developed Solutions

Established a Quick Guide: Created a master tracker with all programs containing critical information

Developed a Background Package: Compiled a comprehensive overview containing the portfolio of programs with essential detail

Created a Communication Forum: Conducted a pilot study of a quarterly portfolio review meeting

Provided Ongoing Maintenance

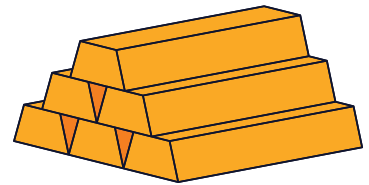
- Scheduled and prepared for quarterly portfolio review meetings and utilized weekly regulatory meetings, created a status dashboard, and consistently reinforced the central location of all the documents

Results:

The company was able to successfully organize their 20+ programs allowing for efficient decision making, timely adaption to changes in strategy, and an understanding of current activities. The regulatory department was able to become well versed on the history, strategy, and current status to mitigate current and future development and regulatory risks, ultimately saving their company delayed timelines and added costs.



Vs



- Scattered information across programs
- Multiple silos without cohesiveness
- Multiple systems leading to confusion

- Organized portfolio
- Collaboration across functions
- Central location to improve communication

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](#)



Halloran Consulting Group, Inc.



@HalloranConsult



Halloran

A ProductLifeGroup Company



hallorancg.com



info@hallorancg.com