



Transforming a Small Pharmaceutical Company from Incubator to Independence



AT A GLANCE

FUZE IT helped an early-stage pharmaceutical company transition from incubator to independent operating environment quickly and efficiently.

CLIENT

A small pharmaceutical company in the midst of an IPO and planning their NDA enabling Phase III study.

CHALLENGES

The client was operating within an incubator relying heavily on shared infrastructure - physical office, phones, email, file system, etc. They did not have an exit strategy and hadn't accounted for the demands of being a public company and ramping up toward potential commercialization. They were approximately 6-12 months behind the curve in acquiring the appropriate human and technology resources to meet the aggressive timelines driven by their efforts to gain FDA approval.



From Incubator to Independence

SOLUTIONS

Karl was brought in to lead this transformation because of his comprehensive understanding of a successful business model spanning the clinical development lifecycle. His methodical and strategic approach ensured uninterrupted business operations, including successful commercial launch.

- Karl began by building the company's IT infrastructure, ensuring no disruption to ongoing operations.
- To enable regulatory and quality assurance capabilities, Karl introduced Veeva Vault for regulatory submissions. Additionally, he implemented a Quality Management System (QMS) and IT Policy framework to support compliance efforts.
- For Clinical Operations, Veeva Clinical (eTMF) was implemented. Karl also coordinated extensively with CROs and sites directly.
- To support finance and compliance, he transitioned the company's financial systems from QuickBooks to NetSuite ERP, implemented proper controls, and guided the audit program, including Sarbanes-Oxley compliance efforts.
- In preparation for the commercial launch, Karl built commercial operations, implementing Veeva CRM, a serialization system, a fleet program, a sales team technology strategy, etc.
- One of Karl's key achievements was his ability to swiftly onboard 70 new employees, seamlessly integrating them into the company's systems, processes, and policies within an impressively short time frame.

Early stage Life Sciences teams need practical experience to navigate complex challenges, agile leadership to accelerate growth, and vision to drive success and bring innovative therapies to market.

BENEFITS

In addition to the tactical solutions implemented, Karl filled leadership gaps in nearly all business units before the client was able to bring in the appropriate resources. His efforts resulted in a seamless transition from the incubator to an independent operational environment. The company gained a robust infrastructure capable of supporting regulatory and quality assurance activities and efficient financial operations with enhanced compliance.

Through his strategic planning, execution, and comprehensive support, Karl significantly accelerated the company's journey towards commercialization, equipping them with the capabilities to thrive independently. His contributions were pivotal in transforming the company from a small, incubated entity to a ready-for-market pharmaceutical player.