propharma

CASE STUDY

Outsourcing QA: Reduce Time and Expense While Meeting Critical Requirements

With ProPharma's expertise, the VPC was able to launch the product without additional overhead or delay.

With the high fixed costs associated with pharma and biotech manufacturing, outsourcing production and other required business processes remains an attractive strategy for many small and mid-sized organizations. This may be the only option for smaller firms who cannot justify the cost associated with building and maintaining physical facilities and procuring the experience and expertise needed to develop, implement, and maintain a compliant Quality Management System. This model is known as a Virtual Pharma Company (VPC).

There is a tendency for VPCs to rely solely on the QC/QA units within their outsourced Contact Manufacturing Organization (CMO) to perform quality functions. However, the sponsor organization has the ultimate responsibility for product compliance, and product quality, safety, and efficacy. This responsibility calls for structuring the organization to exercise proper oversight over manufacturing, quality control labs, quality asurance, regulatory affairs, and project management.

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Contact us to learn how our experienced team can help ensure successful outcomes throughout the product lifecycle.

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challenge

A Canadian-based VPC acquired a product from a major international pharma company in early 2020. The successful technical transfer of the manufacturing process for this product would potentially lead, following FDA approval, to a US product launch.

The company had a solid business plan in place, hired a CMO to handle manufacturing and packaging, but lacked regulatory and quality expertise and capacity.

The VPC established an aggressive goal to achieve a successful technology transfer, and begin manufacturing, packaging and distribution by mid-year 2020. To ensure that rigorous quality and safety standards were met, they committed to assigning the task of QA to a completely different team than the CMO.

The VPC asked ProPharma to serve as their QA unit. They were confident that the outsourcing of QA tasks to a specialized organization meant they could leverage highly competitive and capable resources to realize the timely release of their product in the US market.

solution

ProPharma was engaged to provide not only the technical capabilities needed to execute the project, but the project management skills to deliver on time, meet regulatory requirements, and with the necessary communication to prevent or mitigate a delayed product launch.

To manage a project of this scope, we formed a team of cross-functional experts. The team members served as the primary QA and Project Management representatives and were assigned for the duration of the project.

The project team consisted of QA specialists led by a strategic project manager who had overall responsibility for the project team. With unparalleled talent and industry knowledge, this team functioned as the VPC's QA unit.

The team quickly conducted a gap analysis and addressed shortcomings between the current systems against RA and QMS requirements. We began addressing areas where help was needed, such as matching SOPs with the business needs, writing SOPS, and remediating the product development process in accordance with the developing QMS.

As the launch date approached, ProPharma implemented a Deviation/CAPA and customer complaint system, along with an external supplier audit plan.

results

With ProPharma Group's outsourced QA and Project Management expertise, the VPC was able to launch the product, comply with regulations, pass regulatory audits, and implement their QMS without additional overhead or delay.

As the product lifecycle continued, ProPharma was retained for ongoing support as their outsourced QA unit, working together to augment their capabilities, while keeping their expenses to a manageable level.

Additionally, ProPharma was asked to assume full responsibility for Medical Information and Pharmacovigilance responsibilities and Quality Product Compliant process.

improve the health and safety of patients.

From early concept development through each clinical phase, product launch, and commercialization, we partner with pharmaceutical, biotechnology, and medical device clients to tackle complex challenges. We help to ensure regulatory goals are met, business objectives are achieved, and patient health and safety is improved.

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