Case Study:

QMS Development and Quality Support for a Virtual Pharmaceutical Company

The FDA Group partnered with a virtual pharmaceutical startup to address the unique challenges of quality system development in a virtual operating model. Without traditional brick-and-mortar infrastructure, these organizations must build robust quality systems capable of effectively overseeing external partners while maintaining regulatory compliance.

What began as a focused SOP development project evolved into an 18-month engagement, during which The FDA Group's consultants helped establish a comprehensive QMS, conduct supplier qualification activities, perform distribution center audits, and ensure regulatory compliance through specialized expertise in CMO oversight, complaint handling, and reporting requirements.

The Problem

The company needed to rapidly establish quality systems after acquiring rights to manufacture a critical life-saving drug. With minimal internal staff and primarily outsourced operations, the company faced the complex challenge of building compliant systems while maintaining ongoing production and distribution of its therapeutic product.

The company's newly hired Director of Quality, who had only been with the organization for a few months, initially reached out to The FDA Group seeking assistance with a gap analysis and high-priority SOPs. The Director recognized that the existing QMS was inadequate for the company's growing operations. As a virtual organization, the firm faced significant resource constraints, with Quality operations initially consisting of just one person — the Director himself.

The organization faced multiple interconnected challenges:

- Managing a life-saving drug product with strict timing requirements for patient administration
- Operating virtually with minimal internal staff
- Overseeing a foreign CMO
- Establishing and managing relationships with major healthcare distributors
- Ensuring FDA compliance as a newly formed organization
- Meeting various regulatory reporting requirements
- Managing product stability and lifecycle considerations

The FDA Group's Approach & Solution

What began as a focused SOP development project evolved into a comprehensive Quality partnership spanning nearly two years. The FDA Group established bi-weekly meetings with the client from the outset, ensuring consistent communication and rapid response to emerging needs. The engagement unfolded in several phases:

→ *Initial Phase: High-Priority SOP Development*

The first QA consultant was brought in to conduct a gap analysis and develop critical SOPs. However, it quickly became apparent that the scope of work needed to be broader. The Director, being new to the company and responsible for high-level operations, realized he couldn't manage the full QMS development independently as initially planned.

→ *Comprehensive QMS Development*

The FDA Group deployed a second Quality consultant specializing in building quality systems from scratch. This consultant worked with the client for approximately 18 months, eventually extending to nearly two years, providing two crucial services:

- Development of a complete, right-sized QMS appropriate for a virtual pharmaceutical company
- Strategic advisory support to the Director of Quality, serving as a valuable sounding board for Quality decisions and strategy

The consultant took particular care in right-sizing the QMS, recognizing that while large corporations might need extensive systems, this virtual organization required a more focused approach. They provided options and ideas while allowing the Director to make final decisions appropriate for the organization.

→ *Distribution Center Qualification*

As the QMS development progressed, it became clear that the company needed to establish proper oversight of its distribution partners.

The FDA Group provided a specialist who conducted 4-5 audits of different distribution centers. Importantly, the consultants helped optimize this process, advising that not every distribution site needed to be audited. This ultimately saved the company significant time and resources compared to the initial plan for 10-15 audits.

→ *Additional Specialized Support*

Throughout the engagement, The FDA Group provided several specialized consultants to address emerging needs beyond core QMS development:

- ***CMO Oversight and Expansion:*** The company's primary CMO required significant oversight and support, leading The FDA Group to provide supplementary GMP audit support for this critical manufacturing relationship. As manufacturing capacity needs grew, the company sought to diversify its manufacturing capabilities. The FDA Group provided a consultant based in Italy to conduct supplier qualification activities for a potential European CMO, supporting the team's strategy for geographical expansion and increased production capacity.
- ***Regulatory Reporting and Compliance:*** A focused consulting engagement helped establish the client's CARES Act reporting processes. This project included guidance on the filing process and data accuracy requirements for submissions. In parallel, consultants helped develop robust systems for complaint handling and reporting, creating templates and processes for collecting complaint data and providing required reports to the FDA. This included establishing statistical tracking mechanisms and formal procedures for managing the complaint reporting process.
- ***Product Lifecycle Management***: When faced with decisions about aging product inventory and non-production batches, the company engaged The FDA Group's regulatory expertise to assess options and determine appropriate handling procedures. A consultant provided specific regulatory guidance for managing these materials within compliance requirements.

These additional support activities typically emerged through regular meetings, where the client team identified new needs, and The FDA Group would source appropriate expertise. This pattern of engagement demonstrated the evolution of the relationship from a targeted QMS development project to a comprehensive Quality partnership, with the company consistently turning to The FDA Group as its first resource for emerging Quality and regulatory needs.

Results

The partnership delivered several key outcomes:

Quality System Implementation

- Established a functional QMS appropriate for a virtual operating model
- Created confidence in FDA compliance position
- Developed robust templates and procedures for regulatory reporting
- Provided framework for training incoming Quality staff

Operational Optimization

- Gained effective oversight of the distribution network through targeted audits
- Optimized audit strategy, reducing planned distribution center audits from 10-15 to 4-5 critical sites
- Established efficient processes for complaint handling and CARES Act reporting
- Created sustainable frameworks for CMO oversight

The engagement demonstrated the value of having experienced Quality professionals available during a critical growth phase. The Director of Quality, initially operating as a "Quality department of one," found particular value in having a trusted sounding board for strategic decisions.

As the company built its internal Quality team, it gradually reduced its reliance on consulting support. This transition was natural and strategic, having established the fundamental quality systems and processes needed for its operations. The Director of Quality repeatedly expressed appreciation for the partnership's role in establishing a solid foundation for the growing Quality organization.

The engagement demonstrated The FDA Group's ability to serve as a comprehensive Quality partner, adapting to evolving client needs while providing strategic guidance to help a startup organization build appropriate quality systems efficiently.