Case Study:

Long-Term Quality System Staff Augmentation

In September of 2018, and continuing through to the date of this case study's development in July of 2020, The FDA Group has been pleased to support a large clinical service company's QMS remediation efforts and long-term staffing assignments for two highly-skilled individuals over an extended period of time.

These individuals continue to serve vital roles in the management of the company's quality and pharmacovigilance function, serving as internal full-time resources through a convenient, cost-effective workforce model that circumvents the administrative costs and burdens of traditional hiring.

The Problem

In the lead-up to a series of vendor audits, the company identified multiple gaps in its quality system. However, it lacked the in-house expertise to plan and execute the necessary steps to close them. These shortcomings required a strategic assessment and action plan, as well as practical, day-to-day oversight of the activities included within that plan, such as revising and rewriting procedures from an expert perspective.

This challenge called for an outside resource to fulfill both a traditional consulting role in planning the improvement strategy as well as a hands-on implementation role to put that strategy into practice and manage it going forward.

The company engaged The FDA Group to utilize two of its drug safety and quality system experts who brought decades of regulated life science expertise to plan and execute these work tasks and provide ongoing support as augmented internal resources. The experts brought direct experience and a wealth of documented remediation and regulatory preparedness knowledge in managing pharmacovigilance and broader quality assurance programs.

The FDA Group's Approach & Solution

During the initial phase of the project, the first of the two insourced resources assumed an internal role commensurate with a Manager or Director. This individual conducted a comprehensive assessment of the company's QMS and developed a corresponding strategy for quality system improvement.

During the second phase of the engagement, The FDA Group provided an additional contracted resource to serve as a documentation specialist—drawing on extensive experience to revise and rewrite fully-compliant procedures and other documents in line with the strategic improvements before pushing them live throughout the QMS. Upon completion of the initial documentation project, the expert's wide-ranging skill-set was utilized to broaden the scope of their role into a QA leader—filling in-house skill gaps as a full-time resource, providing consultant-level expertise as well as practical execution capability.

Following the successful completion of the initial document control assignment which began in September of 2019, a follow-up addendum was developed in January of 2019 including the following work tasks:

- Creating, reviewing, and updating SOPs based on operational/technical needs
- Working with senior leadership and department heads to identify needs for new SOPs
- Developing training and evaluation for staff on SOPs
- Cultivating and disseminating knowledge of quality assurance best practices
- Assisting in the development of change control processes, practices, and guidelines
- Providing support for internal and external audits, corrective actions, responses, and follow-up

Following the successful, timely completion of these work tasks, a second addendum was then established to further expand the duties of the contracted resources in January of 2020. This scope of work formally assigned the role of "QA Director," with responsibilities for the company's assurance activities and pharmacovigilance projects.

Just a sample of these deliverables included (and continue to include):

- Implementing and promoting the use of consistent, efficient and quality processes to meet timelines and deliverables according to requirements and standard operating procedures, and assume accountability for the deliverables
- Ensuring compliance of operations with governing regulatory requirements
- Nurturing and sustaining an environment of continuous learning
- Providing ongoing high-level reviews of the pharmacovigilance services which include but are not limited to individual case safety reports (ICSRs), aggregate reports, signal detection reports, risk management plans, literature searches, Medical Information, and Product Quality complaint reporting
- Identifying quality trends and conducting detailed root cause assessment
- Preparing Non-Compliance Reports and managing the Corrective and Preventive Action (CAPA) process
- Ensuring that CAPA results are tracked, implemented, and produce documentary evidence to that effect in coordination with the project managers
- Conducting process review in coordination with the development of process standards for measurements and process improvements

Results

By combining the expertise and strategic thinking of a traditional consultant with the practical on-the-ground execution of a contingent staffing assignment, the company was able to accomplish its immediate project needs and find additional ongoing value through the convenient staff augmentation model.

Following the successful completion of its audit readiness activities, the expert resources placed by The FDA Group went on to play a much larger role in the operation of the company's ongoing quality function—applying extensive drug safety experience to lead its pharmacovigilance program.

Thanks to their broad knowledge bases, both resources secured by The FDA Group continue to engage the company through an extended full-time contingent staffing arrangement—a testament to the convenience and cost-effectiveness of a sophisticated staff augmentation model when combined with niche life science expertise.

Impressions & Feedback

that The FDA Group brought "extreme value" to the project and were able to both expand the original scope and assist in many other areas without the need to supply additional headcount–saving costs in the process.

The time freed through greater efficiencies enabled The FDA Group to take on additional workload, further enabling a reduction in the Company's supplemental headcount and keeping budgets manageable throughout the entire duration of the project.

In addition to the projects described above, The FDA Group is currently engaged with the Company on three other quality system remediation projects, both in the US and the EU.