CASE STUDY: DOMESTIC AUDITING PROJECT

The FDA Group was pleased to have supported a series of Risk Evaluation and Mitigation Strategy (REMS) Audits conducted in both clinical inpatient pharmacies and distribution centers throughout the United States. These assessments evaluated product distribution processes for high-risk healthcare products to ensure those processes were being properly followed and data was effectively communicated to regulators.

THE PROBLEM

Citing a lack of oversight throughout its network of inpatient pharmacies and distribution centers, the Company found itself in need of an external resourcing solution to support its REMS agreements with FDA. As a condition of product approval, regulators required the Company to gather and report on a number of particular data points to ensure high-risk healthcare products were being administered according to stringent requirements.

In this case, the product in question could not be dispensed to pregnant women due to serious health risks. Authorized pharmacies were required to develop and follow a process to ensure women were not currently pregnant––and did not become pregnant––for the duration of their treatment. With a report deadline looming just two months away, the Company approached The FDA Group to utilize its diverse group of experienced consultants located throughout the country to quickly and thoroughly conduct the required REMS Audits and develop a report for submission to FDA.

THE FDA GROUP'S APPROACH & SOLUTION

Working within the short timeline, The FDA Group's project coordinator identified several auditors based on their proximity to the Company's locations and their experience conducting these particular types of audits. All of the experts selected for the project had personal experience successfully conducting REMS Audits and were located near the locations in need of assessment––an advantage which allowed The FDA Group to pass cost savings onto the Company. Each auditor thoroughly reviewed the Company's REMS agreement with FDA in advance and worked together throughout the project to ensure identical audits were being conducted.

REMS Audits were performed at each of the inpatient pharmacies, all managed by The FDA Group's project coordinator, who also provided a single, direct line of contact for the Company. Auditors evaluated each pharmacy's processes to ensure products were only being dispensed to patients who were subject to adequate screening.

RESULTS

Despite an unexpected medical emergency affecting a member of the auditing team which could have resulted in a serious delay, The FDA Group worked quickly to coordinate and arrange a fully qualified and experienced replacement to complete the assessment. The total auditing engagement was completed on time and under budget to the expectations of the Company. Quality personnel were given a clear and actionable report detailing all findings at each site that was assessed.

Since concluding the project, the Company has contracted with The FDA Group to conduct the same assessment for other inpatient pharmacies within the organization for a second year in a row.

IMPRESSIONS & FEEDBACK

Following the engagement, the Company expressed satisfaction and delight in The FDA Group's ability to deploy consultants who had extensive personal experience––an advantage that provided a sense of confidence throughout the process.

The Company also expressed satisfaction with the auditors' ability to complete the project with very minimal input from their team, thereby reducing their time and labor commitments significantly.

Any conversations between internal personnel and The FDA Group's auditors and project coordinator were described as being educated and informed at each step during the assessment. Expectations were clearly communicated from the very start, providing a comfortable working atmosphere while easing tensions under the pressure of short deadlines.

Given the uniquely wide range of geographic and knowledge-based diversity among its consultants, The FDA Group was able to select the right experts for this particular project and escalate unexpected on-site staffing issues immediately––an ability afforded by a large staff of former FDA personnel and industry experts who are prepared to take on virtually any auditing task.