



CASE STUDY: INTERNATIONAL AUDITING PROJECT

For two calendar years in a row, The FDA Group was pleased to have supported a large healthcare product Company's Quality & Regulatory (Q&R) Audit Project encompassing multiple sites located around the world.

THE PROBLEM

In managing a variety of sites throughout the world, the Company's corporate leadership expressed growing concerns over the quality systems within some of their operations. Specifically, senior leadership worried many of these systems may not have been meeting corporate expectations. These concerns were exacerbated by a growing trend toward more frequent overseas FDA inspections as well as a general need for standardization across the organization.

In order to reach beyond the capabilities of their internal auditing team to better understand FDA expectations, the Company approached The FDA Group to gain the unique advantage of utilizing its former FDA investigators to provide honest and accurate quality system assessments as well as handling a number of pressing compliance issues requiring immediate attention.

THE FDA GROUP'S APPROACH & SOLUTION

During the first year of the project, 37 Quality Management System (QMS) and focused product compliance audits were conducted ranging from five to six working weeks each at the Company's request. Over the next year, 33 QMS and focused product compliance audits were performed ranging from three to seven weeks, again at the direction of the Company.

These projects required full time project management as well as the need to source and qualify third party auditors with sufficient skills and experience. The FDA Group satisfied that requirement by bringing experienced former FDA personnel into the project as leading consultants.



In addition to the projects described above, The FDA Group was utilized by the client for GCP audits as well as many “special audits” conducted around the world pertaining to Warning Letters and other “high profile” situations. The FDA Group is currently involved in large remediation projects for the Company.

RESULTS

For the auditing project in the first year, The FDA Group was pleased to announce completion at **20% under the estimated budget.**

Similarly, for the auditing project in the second year, The FDA Group was again pleased to announce completion at **29% under the estimated budget.**

In working alongside former FDA investigators from The FDA Group, the Company's internal audit team was able to broaden their knowledge and expertise regarding FDA expectations and policies—empowering them to improve their own auditing procedures and bring a higher level of scrutiny to quality system and record review.

IMPRESSIONS & FEEDBACK

The unique advantage of leveraging the unparalleled knowledge and experience of a former FDA investigator brought an added level of effectiveness to the Company's auditing functions while ensuring quality system consistency across dozens of domestic and international sites.

More specifically, the presence of a former FDA investigator in a leading consultative role eliminated potential questions regarding the efficacy and/or value of particular actions or suggested corrections related to quality system management and recordkeeping.

The FDA Group's ability to bring new consultants in and get them rapidly up to speed is a unique advantage The FDA Group brings to each of its projects.

Among the many praises we have received from the Company employees, we find that most commonly we are complimented for our ability to **select the right people for a particular project, provide a responsive and flexible working relationship and execute on time and within or under budget.**

