



CASE STUDY: INTERNATIONAL AUDITING PROJECT WITH WORLDWIDE CONSULTANT RESOURCING

The FDA Group partnered with a semi-virtual healthcare product Company to support a series of international Quality Audits to assess both Good Manufacturing Practices (GMP) and Good Clinical Practices (GCP) throughout the United States, Europe, Asia, and the Middle East.

THE PROBLEM

As a semi-virtual manufacturing organization operating several divisions internationally, the Company lacked the internal staffing and resources to conduct a series of necessary GMP and GCP audits against both national and international quality standards. The Company was in need of a third-party consulting firm capable of staffing a large auditing project and completing the project within five months.

Despite the challenge it posed, transparent communication was an absolute necessity. Auditors needed to coordinate with central management to ensure each assessment was proceeding according plan simultaneously. This presented a particularly difficult challenge across multiple time zones.

THE FDA GROUP'S APPROACH & SOLUTION

The FDA Group identified and selected almost a dozen auditors offering specific expertise to address the particular needs in each international location.

In addition to their areas of experience and expertise, The FDA Group was able to choose from a large group of international resources to locate capable quality professionals in each local market, thereby avoiding additional costs to the Company for long-distance travel arrangements.

The FDA Group's project coordinator managed the project very closely to ensure each milestone was being met according to plan and relaying all information to Company points of contact.



RESULTS

The audits provided insight into particular areas of concern for sites around the world. Each of the GMP and GCP Audits, and subsequent reports generated, offered Company and department leaders clear and practical information regarding the strengths and weaknesses of their quality system as they related to both national and international quality standards.

The Company continues to engage The FDA Group for its GMP and GCP auditing needs.

FEEDBACK & IMPRESSIONS

The Company's Quality leadership team has expressed satisfaction regarding the audits being completed at each of its international divisions, especially given the steep challenges posed by the international scale of the work.

Company leaders were particularly impressed by the level of organization and project management, which is rarely seen during simultaneous auditing projects of this kind.

Using a centralized project coordinator as the primary point of contact, the Company avoided the challenges of working with multiple auditors in sites around the world. No matter how large or small the project, The FDA Group prides itself on tailoring the structure of its engagements to minimize the burden on its clients, while offering world-class expertise wherever it is needed.

