



Case Study:

International PAI Audit Preparation & Remediation Project

The FDA Group was pleased to have supported a large healthcare product Company's Pre-Approval Inspection (PAI) audit preparation project and subsequent quality system remediation efforts at a site within the European Union (EU). The FDA Group completed this project **on time** and **15% under budget**.

The Problem

In the lead-up to a PAI conducted by the United States Food and Drug Administration (FDA), the Company detected a number of quality system gaps related to a backlog of open deviations, Corrective and Preventive Actions (CAPAs), and insufficient processes for ensuring data integrity throughout its production operations.

Citing a lack of internal resources with direct experience conducting comprehensive audits and quality system remediation, the Company engaged The FDA Group to utilize its quality system experts, who combined, brought more than eight decades of regulated expertise to plan and execute a Q&R audit preparation project and close quality system gaps through deviation reduction activities. The experts brought not only decades of direct experience but a wealth of documented remediation and regulatory preparedness expertise.



The FDA Group's Approach & Solution

During the initial phase of the project, The FDA Group provided training, executed deviation reduction activities, and conducted process mapping to identify opportunities for improving the Company's data integrity practices.

Over the following two months, The FDA Group implemented process improvements to strengthen the Company's data integrity practices, ensuring systems were in compliance and adhered to Company standards.

Over the following month, The FDA Group assembled an audit storyboard for guiding assessment activities and led in-depth audit preparation training.

In the final month of the project, The FDA Group finalized the Company's audit preparation activities, which culminated in a mock audit designed to mirror the forthcoming PAI.

Throughout the duration of the project, The FDA Group drew on its extensive experience to carry out several activities in support of the Company's project goals. These included conducting deviation investigations, performing root cause analyses, implementing CAPAs, improving and refining processes, assembling audit storyboards, and providing both subject matter expert and audit conduct training.

This project required full-time project management as well as the need to source and qualify third party quality system experts with relevant skills and experience. The FDA Group satisfied these requirements by bringing four quality and regulatory specialists with a combination of FDA and industry expertise into the project as leading expert resources to investigate, close, and remediate quality system gaps and prepare the company for its forthcoming FDA investigation.



Results

The FDA Group was pleased to announce project completion **on time** and **15% under the estimated budget**.

Thanks to The FDA Group's rapid deployment of qualified resources, the Company was able to expand the scope of its original project plan, which had included only the deviation and CAPA reduction activities to also incorporate data integrity process improvement and overall PAI readiness. The FDA Group's ability to provide the right experts at the right time throughout the project also enabled the Company to eliminate the need for additional supplemental staff, enabling further cost savings.

Drawing on a deep understanding of regulatory expectations, The FDA Group was uniquely positioned to assist the Company with additional gaps identified throughout the project. For example, The FDA Group discovered that several internal subject matter experts did not possess the experience or qualifications necessary for understanding audit expectations and maintaining proper audit conduct.

The FDA Group assisted these individuals by providing tailored storyboard development and audit training. These exercises provided valuable opportunities for internal staff to experience mock audit scenarios that they otherwise would not have had while empowering them to reinvest these competencies in strengthening their quality system management practices going forward.

Impressions & Feedback

Company leadership expressed a strong sentiment of satisfaction, remarking 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.

