



An Oxford Case Study

Preparing for an FDA Inspection

FDA Readiness with Quality Experts, Ready on Demand

The Challenge

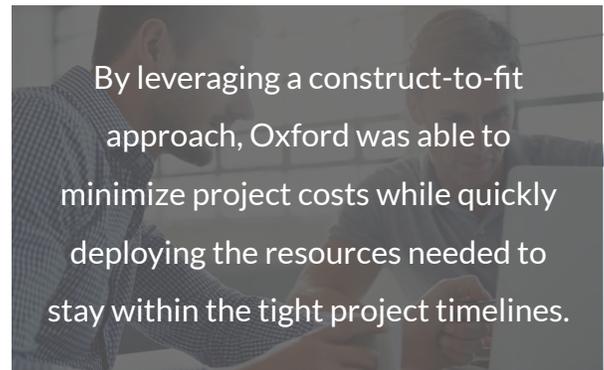
A client needed to pass an impending FDA inspection. Pro-active FDA readiness remediation in the following areas were needed: CAPA, TMV, Process Documentation, and Training. They required a team of Compliance & Quality Assurance professionals proficient with performing and creating robust sustainable Quality Management System (QMS) documentation to accomplish the remediation. The client was faced with a tight timeline of 7 weeks to complete the project to coincide with the impending FDA inspection.

The Solution

Compliance and Quality Assurance professionals were deployed to evaluate, then remediate processes, programs and the requirements of the client's Quality Management System. Eight resources, including the Project Manager, were rapidly mobilized and deployed to detect, correct, and identify improvements to eliminate the risk of non-compliance and prevent future deficiencies. Project governance was provided through an Oxford Project Manager and the development and execution of a project plan. Documented procedures, processes and records in compliance with 21CFR Part 820 and applicable Subparts of the regulation were related project deliverables.

The Result

The Oxford team successfully remediated all current processes and procedures so the client was compliant with the requisite FDA regulations and International standards. By leveraging a construct-to-fit approach, Oxford was able to minimize project costs while quickly deploying the resources needed to stay within the tight project timelines. Once engaged, project oversight was provided for strict adherence to the scope and schedule. The client's Executive Management communicated their praise for providing them with a sustainable, maintainable and compliant Quality Management System within the stated budget and schedule.



About Oxford

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