Ready for inspection, on time and on budget.

Case Study

Remediation for FDA Readiness

INDUSTRY

Life Sciences

SERVICES

Quality Assurance Engineering

Compliance

Remediation

Auditing

SKILLS

21 CFR Part 820 & Subparts

FDA Regulations

Quality Management Systems (QMS)

Project Management

The Challenge

Our client needed to pass an impending FDA inspection. Proactive 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 seven 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 our Project Manager and the development and execution of a project plan. Documented procedures, processes and records in compliance with 21 CFR Part 820 and applicable Subparts of the regulation were related project deliverables.

Our project oversight provided for strict adherence to the scope and schedule.

The Result

Our team successfully remediated all current processes and procedures so the client was compliant with the requisite FDA regulations and international standards. By leveraging our construct-to-fit approach, we were able to minimize project costs while quickly deploying the resources needed to stay within the tight project timelines. Once engaged, our project oversight 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.

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