

# PROJECT MANAGEMENT

## Regulatory Compliance Remediation – The Case Study



### *The Customer*

Contract pharmaceutical manufacturing company with multiple sites in North America.

### *The Situation*

Customer had been challenged by the Food & Drug Administration and other external regulatory agencies through warning letters and inspection reports to improve the execution of its quality processes. The customer had been unable to resolve problems that had been identified and agreed to by the various agencies. As a result, the customer was in danger of not meeting key milestones and suffering severe consequences from the agencies.

Additionally, the company had retained numerous firms to help support the remediation effort, and had incurred substantial costs and was on a path to spend approximately 400% of the original estimated costs.

Since these issues were a result of formal inspections, the findings were in the public domain. The company was at additional risk of losing existing customers and was also having difficulty attracting new customers.

### *The Strategy*

The company recognized that they were in an increasingly critical situation and that a change in strategy was required in order to recover lost time and complete all required changes in a now shortened timeframe.

i-Solutions was engaged to design the new approach, and provide strategic, as well as tactical support, and to manage all elements related to execution and cost controls.

### *The Results*

i-Solutions provided a variety of solutions to this customer. Our professional staff worked closely with the company's Chief Executive Officer and Senior Management team to accomplish the following:

- Applied rigorous project management techniques to ensure that past audit findings

and customer complaints were properly resolved and reported back to the appropriate regulatory agencies. Thousands of findings and complaints were resolved and the backlog of responses was eliminated.

- The company received accolades from the regulatory agencies for their marked turnaround and for achieving the remediation targets. The prior spend rate was reversed, and the project was completed under budget.
- The company had developed and implemented a state of the art Quality Management System that addressed all systematic issues relating to quality operations and which minimized any future risk of adverse regulatory agency findings.

Due to the successful results, the company was able to retain a majority of their existing clients and once the remediation had been successfully completed, was able to aggressively resume building its client base.

### *The i-Solutions Advantage*

i-Solutions was integral to the design, implementation, and execution of the programs deployed in support of this key business recovery initiative. Our thorough knowledge of the industry, knowledge of core business processes, and deployment of our tools and our programs, allowed for rapid deployment, reliable implementation, and predictable results.

i-Solutions has the expertise and experience to support a wide range of project types in a variety of ways from designing new project management systems, to auditing existing project activities already underway, to consulting services on any and all aspects of the project management process. Our services are provided by seasoned professionals with practical industry experience, including pharmaceutical, and are designed to ensure the ultimate success of your business strategy.