

CASE STUDY: Streamlining Compliance: Enhancing Transparency in Pharmaceutical Reporting

Background:

The Client, a small pharmaceutical manufacturer active in the U.S. market since its first product launch, engaged QPharma to evaluate its adherence to federal and state transparency regulations. The evaluation focused on assessing the company's approach to identifying relevant activities, capturing data, mitigating errors, and refining reporting methodologies. Recognizing the need for a comprehensive review due to changes in staffing and vendors, the Client aimed to harmonize data capture across the organization and integrate industry best practices to enhance efficiency and cost-effectiveness.

Challenge:

- The Client had an informal program in place but lacked specific procedures for on-going management of the program
- The Client was concerned that data may be missing or inaccurate in its reports
- Due to staffing changes certain questions about historical reports and decisions made regarding those reports were a concern

The client required a comprehensive overhaul of their informal transparency compliance program to ensure accurate data management, align with regulations, and integrate robust frameworks to rectify data inaccuracies and historical reporting issues.

QPharma's Solution:

QPharma employed its proprietary methodology to thoroughly assess the client's transparency compliance, focusing on program activities and data capture processes. The project included initial stakeholder meetings to define scope, followed by regular documentation reviews and compliance evaluations. A detailed gap analysis led to a draft report with prioritized recommendations for risk mitigation and process improvements. This culminated in a roadmap for implementation and a final report, with QPharma continuing to offer consulting for ongoing enhancements.

Titanium® Results:

- Enhanced confidence in compliance to Spend and Sample Regulations
- Data analytics for enhanced monitoring to ACA 6002, ACA 6004 and PDMA regulations
- Minimized operational disruptions during the transition
- Aligned operations with best practices, improving overall efficiency and cost effectiveness