NAVIGANT

LIFE SCIENCES

Life Sciences Disputes, Compliance and Investigations – Monitorships, Oversight and Compliance Effectiveness Testing

Regulatory enforcement agencies continue to pursue industry settlements, with increasing oversight requirements. Companies need to secure oversight that represents an intimate knowledge of the laws and regulations of the industry and how each of the functional areas within a Pharmaceutical, Biotech, Medical Device and Diagnostic company operate within the related risk environments. Navigant professionals have the experience required to assist clients in achieving the necessary reporting obligations related to settlements.

THE CHALLENGE

INDEPENDENT COMPLIANCE REVIEW

THE SOLUTION

A global bio-pharmaceutical company entered into a Corporate Integrity Agreement that required an independent compliance expert. The Navigant team rapidly established independence and objectivity with the company and the Office of Inspector General (OIG), established a work plan based on OIG guidance and the seven elements of compliance and executed the Compliance Effectiveness Review. **Our expert report provided the necessary information for the Board to reach their resolution, while providing the company practical, recommendations on how to improve the effectiveness of the compliance program.**

THE CHALLENGE

COMPLEX IRO REQUIREMENTS

THE SOLUTION

A global pharmaceutical company had entered into a Corporate Integrity Agreement (CIA) that required an Independent Review Organization (IRO) be appointed for five years. The review included among other things, a system review of Government Pricing, fee-for-service arrangements with physicians, sales force compensation, and a transaction review of payments to U.S. based physicians, sampling, call plans and off-label inquiries. **Navigant served as IRO, secured approval for the work plan and delivered the annual report in accordance with CIA requirements, while providing advice on relevant improvements.**

THE CHALLENGE

PHRMA CODE EXTERNAL VERIFICATION REVIEW

THE SOLUTION

An internationally based bio-pharmaceutical company required an external validation of their PhRMA Code based compliance program. The company is also under a Corporate Integrity Agreement and recently completed year 1 of their reporting requirements. **The Navigant team provided a comprehensive PhRMA Code Review, leveraging the IRO Report, limiting the need for additional verification and providing a cost effective, rapid and comprehensive review. Timing for the PhRMA Code review has been aligned with the IRO system review timing, further assisting the company to leverage pre-existing requirements for review.**

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About *Navigant, Inc. (NYSE: NCI) is a specialized, global expert services firm dedicated to assisting clients in creating and protecting value in the face of critical business risks and opportunities. Through senior level engagement with clients, Navigant professionals combine technical expertise in Disputes and Investigations, Economics, Financial Advisory and Management Consulting, with business pragmatism in the highly regulated Construction, Energy, Financial Services and Healthcare industries to support clients in addressing their most critical business needs.*

Navigant provides a full range of services to assist life sciences companies with monitorships and the improvement of relevant aspects of their compliance programs through practical and client-specific recommendations. We have been supporting life sciences companies with monitorships since they began in the late 1990's.

OUR EXPERIENCE INCLUDES:

» Assisted a global medical device company through a Deferred Prosecution Agreement, providing the Federal Monitor with a six month and eighteen month Compliance Continuous Improvement Assessment Report.

» Provided a major bio-pharmaceutical company with a Mock IRO review in anticipation of an IRO experience. This enabled the Company to rectify gaps in their systems, including sourcing the relevant data for a complete review. The actual IRO review was successfully completed with a number of actions taken by the Company to ensure successful delivery of relevant data for the purposes of the IRO review.

» Supported outside counsel of a major medical device company with an investigation of Healthcare Professional arrangements in anticipation of a settlement with the Department of Justice and OIG. The investigation uncovered a number of weaknesses that were addressed before the settlement, reflecting the company's commitment to fixing any problems that led to the original allegations.

» Independently evaluated Fair Market Value assessments of fee-for-service arrangements and clinical trial agreements between a major medical device company and Healthcare Professionals for a Federal Monitor.