Regulatory, Tax and SOX Compliance for Biopharmaceutical Company Expanding U.S. Presence



When a United Kingdombased company moved its headquarters stateside, leadership partnered with Cherry Bekaert to assist with compliance and regulatory requirements, and for guidance on future audit preparation.

Company Background

The company is a clinical-stage biopharmaceutical business developing a solution for chronic respiratory illness that aims to obtain approval as a maintenance drug in the United States.

Assessing the Situation

The company moved their leadership and headquarters to North Carolina and needed a U.S.-based advisor to assist with meeting regulatory and compliance requirements including Sarbanes-Oxley (SOX) because they did not have their own internal audit team. Cherry Bekaert determined that while the company currently classified as a smaller reporting, emerging growth company, it was likely that within the year it would move into large, accelerated filer status, and have increased SOX 404b compliance requirements.



Becoming Trusted Advisors

Cherry Bekaert was engaged to perform two initial projects proposed to help the pharmaceutical company better position themselves for future audits: data validation procedures and a review of the company's IT general controls.

The success of the first two projects resulted in the company entrusting Cherry Bekaert with additional advisory support. During the first half of 2023, Cherry Bekaert provided internal control over financial reporting (ICFR) rationalization and process narrative build-out services and the company's 2023 SOX 404b assessment.

The company has since enlisted Cherry Bekaert to provide guidance on fair value of debt disclosure, evaluate the company's U.K. tax process and, in May 2023, Cherry Bekaert assisted the company with a new enterprise resource planning (ERP) software implementation. Cherry Bekaert connected the company with partners who could assist with choosing a new ERP. Company leadership performed their due diligence and opted for a program that Cherry Bekaert knew from experience would create a bumpy transition. Leveraging our accounting and ERP experience, we were able to shadow the implementation across the 90-day timeline, assist with data migration, perform segregation of duties and recommend standard operating procedures (SOPs) to ensure a smooth transition.

Guiding Your Business Through Complex Matters

By building trusted relationships, Cherry's Bekaert's <u>Audit</u> and <u>Risk and Accounting Advisory</u> teams can guide your business through a variety of compliance and regulatory requirements including SOX 404(a) and <u>SOX 404(b)</u>, digital transformation, and tax matters positioning your organization for future success.

Related Guidance:

Examining the Differences Between SOX 404a and 404b

SOX Offshoring: Benefits and Key Considerations From the Service Provider and Client Perspectives

A Guide to Outsourcing the Internal Audit Function

About Cherry Bekaert

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