pharmaceutical COMPLIANCE MONITOR

On the Road to Compliance, a CPA Firm is a Biotech Entrepreneur's Best Friend

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For many pharmaceutical and biotech startups, the ultimate goal is to go public or be acquired by a larger company in the industry. To get the best deal, you'll need the most accurate and verifiable records possible.

Along the way, there are plenty of hurdles to be cleared, including fundraising benchmarks, research and development breakthroughs and a series of FDA approvals. With each step in this long journey, the dream inches closer to reality and, financially speaking, the organization becomes more valuable. But it can take years.

The FDA approves an average of 40-50 medical devices each year for clinical use through the 510(K) standards or the more rigorous PreMarket Approval (PMA) pathway. The approval of synthetic drugs, biotechnology solutions and medical devices all require strict compliance to FDA guidelines, starting from the research and development stage to the preclinical and clinical trials and all the way to final device manufacturing and marketing.

For a small medical device company like NuVascular Technologies, the development of Class II and Class III cardiovascular devices, which require 510(K) and PMA approvals, respectively, can be quite costly. They demand strict compliance to the FDA code of regulations (21 C.F.R. 820) and various ISO standards that require a quality management system (QMS), which has traceability at every stage of the device's development.

It would be awfully expensive to repeat the tests and research if the initial work was not done in compliance with FDA standards. That would mean higher costs and lost time in an increasingly competitive market. As a small company with a limited number of people wearing multiple hats during the device development stage, it is extremely challenging to account for every single regulation requirement while trying to constantly improve upon the final product. In order to ensure the quality of research is not hindered, the final device approval is not jeopardized and the overall cost of the device development is kept at a reasonable level, outside regulatory and quality assurance experts are invaluable. These service providers specialize in regulatory, QMS and reporting – helping to control costs and resulting in a capital efficient business model.

While a start-up biotech or medical device company maintains the much-needed focus on product development, it also is imperative to ensure the "back-office" is well-maintained. This includes implementing core contract and data management, recordkeeping and financial reporting controls. Contract and data management is key to managing development partners, research and development activities and expenditures and, ultimately, the results of such things as clinical trials. This information will need to be readily available as it may be requested by a regulatory body such as the FDA during the approval processes.

Of course, accurate financial reporting is a must when dealing with investors who often like to know how their money is being spent to achieve the organization's objectives. While most expenditures at an early-stage company are for research and development as well as basic administrative expenses, investors will need to

consider progress on development versus expected burn rates of cash. As later-stage investors join in, there are likely to be more sophisticated requests for frequent and clear financial reporting.

When facing the typical exit plan through an IPO or strategic acquisition, a company facing such a potential transaction will be able to readily respond to due diligence requests from legal counsel, underwriters, investors and the SEC if it has maintained good record retention and accounting practices throughout. Inquiries and requests for documents can be quite extensive, covering an array of topics ranging from the actual development of technology to accounting, tax, legal, personnel and other regulatory matters. The inability to provide information quickly and completely can cause delays, or even cancellation, of a potential agreement.

Companies that develop stellar technologies *and* maintain rigorous accountability standards in their document retention are often rewarded with an extra premium in their valuation as transaction partners appreciate the ability to conduct in-depth analyses of the company in a short period of time.

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Managing Partner

Wayne R. Pinnell

As managing partner, Wayne oversees the overall strategic direction and operations of the Firm, while continuing to serve clients in his role as an audit partner.

Before joining Haskell & White in 1995, Wayne spent more than 10 years at BDO Seidman, LLP, rising to the level of partner prior to his departure. He has experience in a wide variety of industries, including technology, manufacturing, wholesale distribution, retail, real estate, and specialized services.

Wayne's clients have included both publicly traded and privately held firms, ranging in size from small, family-owned businesses to corporations with revenues in excess of $300 million annually. He has assisted clients with initial public offerings and the periodic reporting requirements of the Securities and Exchange Commission; private finance and merger/acquisition transactions; and Sarbanes-Oxley compliance. Wayne has also consulted with a number of companies on their general business operations including workflow, waste reduction, strategy, and growth/profit initiatives.

Wayne graduated Magna Cum Laude from Seton Hall University in South Orange, New Jersey, where he received a Bachelor of Science in Business Administration degree.