Skyland Analytics

Life Science Product & Process Data Intelligence

Maximize Exit Valuations and Mitigate Risks in Your BioPharma Portfolio

R&D discoveries and clinical efficacy remain the key drivers of success in biopharma portfolios. But there are trends that are increasing the impact that manufacturing – and related data management – have on portfolio company valuation and liquidity options.

The near universal reliance on contract manufacturers (CMOs) and the FDA's focus on data integrity issues in drug manufacturing have generated unprecedented scrutiny into manufacturing operations by the FDA, strategic acquirors and the SEC. Despite outsourcing manufacturing, the owner (sponsor) remains liable for meeting the FDA's standards for product quality, demonstrating control over the CMO and the drug manufacturing process, and establishing an inscrutable, high integrity process, product and quality data set.

Two challenges must be addressed in order to achieve compliance.

Securing the appropriate level of legal rights related to data transparency, IP and reporting. Be aware that not all attorneys are meeting best practices standards in their negotiation of supply and quality agreements.

Establishing a data management strategy that addresses the challenges created by relying on an extended, external supply chain.

There are a few noteworthy events that highlight the significance of manufacturing and data management/integrity in biopharma operations. One is Fresenius' termination of its $4.5 billion acquisition of Akorn over data integrity issues related to one drug product. Over the last five years, most of the FDA's warning letters have been for data integrity in operations. Additionally, the SEC has indicated that it will be reviewing the sufficiency of the 10b-5 disclosures made by life science companies related to their outsourced development and manufacturing operations.

Investors and boards need to be informed on these issues and ensure that their management teams institute best practices for outsourcing and data management.

As a former biotech executive and general counsel, I look forward to discussing with you ways to mitigate risks in your portfolio. Part of the solution is the Skyland PIMS® process and product data management platform, an FDA-compliant solution designed for collaboration between drug sponsors and CMOs and the management and analysis of data throughout the drug product life cycle.

To schedule a discussion, please email engage@skylandanalytics.net