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As a seasoned professional in the field of chemistry, manufacturing, and controls (CMC) due diligence, I have had the opportunity to work with various investors, including venture capitalists, equity and royalty firms, technology innovators, and product companies looking to expand their pipelines. Over the years, I have observed a growing need for thorough CMC due diligence to ensure the success of pharmaceutical deals and investments.

The triumvirate of Clinical, Commercial, and CMC aspects forms the foundation of a successful drug product and its associated deal. Neglecting the CMC leg can lead to significant problems down the line, jeopardizing the development, manufacturing, regulatory approval, and delivery of a high-quality product to patients.

While many investors may not fully grasp the importance of CMC and related technical and compliance expertise, the industry's most astute investors recognize its critical role. CMC issues may not always present a binary risk compared to clinical or commercial success, but ignoring CMC risk altogether can be a costly mistake.

In my experience, approximately 10% of deals are likely to be impacted by CMC issues that could potentially kill the deal or require significant CMC competencies to save it later. Moreover, I have observed a correlation between poor commercial prospects and CMC issues in drug products. Organizations that excel in one area tend to perform well in others, and the reverse is often true as well.

Throughout my career, I have encountered various scenarios that highlight the importance of CMC due diligence:

1. In one case, a marketed oral dosage product faced ongoing technical problems. The new registration holder, a multinational company, failed to give sufficient notice before abandoning the product and lacked the technical competence to resolve the issue. As a result, the senior secured investor was left to deal with the consequences and needed to return the product to market as quickly as possible. By forming a new company and leveraging CMC expertise, we were able to solve the technical problem, revalidate the process, rebrand, and re-launch the product to the market in just three months.

2. In another instance, a product company went into Chapter 7 bankruptcy due to mismanagement and declining sales. Retaining key personnel and maintaining product

controls and documentation was crucial to preserving the product's registration during the transition to a new company.

3. Lastly, a major multi-national company was out-licensing a biologic asset. Our cost of goods (COGS) analysis revealed that the numbers provided by the license holder were too low, making the deal untenable for the indication. By identifying this issue, we helped the company avoid a potentially catastrophic investment.

In conclusion, CMC due diligence plays a vital role in the success of pharmaceutical deals and investments. Investors must recognize the importance of companies having highly competent and experienced CMC professionals on their due diligence teams to identify and mitigate potential risks, ultimately safeguarding their investments and ensuring the delivery of high-quality products to patients.

We will continue to explore CMC due diligence for investors on the Windshire **blog**. For any due diligence or audit needs, please reach out to **Windshire** or **Labshire**.