



Custom Manufacturing and Fine Chemical Sourcing
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Maximizing VC Investments through Custom Chemistry: Case Study Primer By Christopher Kulp and Linda Tedeschi Miller

In order for privately funded, emerging technology start-ups to succeed, novel technologies must be developed and advanced in an accelerated manner. Venture Capitalists (VCs) can increase their ability to achieve a better and faster return on this type of investment when they recommend the services of an experienced outsourcing provider such as Richman Chemical (RCI). With over

VC Recommendation Saves the Day for Scuffling Start-up

A general partner in a well-respected venture capital (VC) firm was referred to Richman Chemical (RCI) by a fellow colleague within the private equity industry. The VC's funded biotech start-up was facing the pressure of a make or break deadline for keeping the firm afloat. The start-up had an Investigational New Drug (IND) that had already been submitted to the FDA; however, the technical package contained vague data and there were no satisfactory cGMP reference standards. With time at a severe premium, the partner contacted RCI directly and connected the biotech firm with the right external resource to save the project.

Utilizing its 30+ years of industry experience, RCI completed a comprehensive evaluation of the technical package and identified the weak links. Under RCI's direction, clinical trial batches were prepared alongside reference standard preparation and validation. Additional tests were performed for the end formulation, concurrent with stability testing of the active compound. A dialogue was established with therapeutic and delivery mechanism experts to ensure a product suitable for clinical trials. **The end result was a successful FDA review and a grant of fast track status, and an influx of additional funding for the biotech start-up.**

30 years of experience working with early stage companies to develop and commercialize new technologies and products, RCI serves as an excellent resource for VC-financed firms in need of critical, chemistry-based outsourcing services. By becoming an important partner to both early stage businesses *and* the VCs that fund them, RCI assists in accelerating chemistry-based product development, the sourcing of key raw materials, coordinating pilot and full-scale production activities, and reducing the overall commercialization timeline. This

decrease in expended time almost always translates into tremendous cost-savings for start-up clients: in an era of budget optimization, RCI's inherent value with regards to efficient outsourcing services cannot be over-emphasized.

Without a well-established and highly respected partner to provide superior custom chemistry services, a start-up life science firm, for example, places its intellectual property advantage in severe jeopardy. Further, the VC firm's large capital investment, and thus the start-up's overall solvency, is likewise compromised.

To illustrate these points, the following true-life case studies emphasize the importance to

Board Addresses Virtual Firm Needs via Scale-up Experts

While sitting on the board of an East Coast-based virtual firm start-up, a VC contacted RCI after learning of its services at a local biotech conference. The virtual firm needed to manufacture preclinical and validation lots of its proprietary API. However, the investors had imposed a very aggressive timeline relative to the significant scale-up challenges posed by the current process technology. Fortunately, RCI's experienced project manager possessed the crucial skills to identify the key technological hurdles and thus guide the client through successful process improvement work. RCI went a step further and devised a contingency plan to employ the historical process methodology should the new processing technology not progress as quickly as anticipated. The transition from a non-optimized process to a more practical and efficient manufacturing scheme greatly accelerated the company's API commercialization timeline. **Ultimately, expediting the process allowed the VC to develop an optimally profitable exit strategy plan well ahead of schedule.**

RCI Consolidates Custom Manufacturing for University-based Start-ups

The Technology Transfer Office (TTO) of a major East Coast university recently assisted three start-up biotechs originating from the school's chemistry and pharmacology departments. While the major products at each firm differed greatly, the core technology of each was predicated on an identical chemical platform. After speaking with Richman Chemical at an outsourcing and licensing conference, the TTO in charge recommended RCI to the technology officers of each start-up in order to consolidate the availability and minimize the costs of the key chemical raw material. This approach helped to maximize the limited private equity dollars available from the three start-ups. **RCI's recognition of the time and cost sensitivities relevant to university-affiliated and seed money-supported start-ups is crucial for success!**

early stage firms of successfully selecting the proper outsourcing partner. Whether it boils down to in-depth chemistry knowledge and engineering experience, or a

systematic approach to efficient and logical project management, these three case studies demonstrate the best practices approach employed.

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