



Custom Manufacturing and Fine Chemical Sourcing
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Guiding Emerging Technology Companies: A Case Study Primer

By Christopher Kulp and Linda Tedeschi Miller

It can be difficult for emerging technology companies (ETCs) to navigate the terrain of potential chemical outsourcing providers, especially when it feels as if a map and personal trip advisor are necessary to help find the way. Biotech start-up firms can be caught off guard by the skyrocketing costs of infrastructure and manufacturing well before their products are achieving commercial success. For this reason, many new life science companies select the virtual route by becoming “idea” firms that outsource their development and clinical pipelines. However different the business plan or organizational strategy, getting to know the outsourcing company and establishing a comfort level is paramount since successful partnering will play a huge part in the ultimate success or failure of the ETC. It is crucial that such companies find the right outsourcing partner for each aspect of their business.

RCI case studies demonstrate how:

- its client-centered business model yields success;
- its experienced project management staff and proprietary knowledge of the fine chemical and pharmaceutical industries are integral to obtaining the highest quality outsourcing solutions;
- the firm offers a high-quality consortium of laboratory and production sites in order to find the *best* technical fit for any ETC;
- clients consistently utilize and partner with RCI to attain significant cost savings and reduced project timelines.

In most cases, ETCs outsource to free resources in order to focus on core technology development; hence, the overall commercialization timeline can be condensed. Professionals with pilot and manufacturing experience, validated business models, long-term credibility and proven records of accomplishment can reduce the time it takes to bring new technologies and products to market.

To that end, Richman Chemical Inc.(RCI), a leading custom chemical manufacturing and product sourcing service provider, utilizes actual case studies (minus identifiers as dictated by confidentiality agreements) to better acquaint prospective customers with its services and range of experience.

Case Studies

The Dreaded Lab Procedure

A customer came to RCI looking to scale-up from the laboratory to the commercial production scale. A step-by-step list of process steps was provided. The problem? The process steps were not scaleable. The bench chemists were not familiar with the capabilities of the chemical manufacturing facility; therefore, their work was not easily transferable. In addition, the lab used raw materials that were not commercially available.

After careful review of the process, RCI's project team properly scaled the process to achieve successful manufacturing at the commercial level. Further, utilizing its extensive raw material sourcing network, RCI secured significant cost savings on the commercial scale via the procurement of less expensive starting materials. Ultimately, the unit cost of the final product fell under its mandated target and made it an attractive option in the end user market.

Lesson learned: A complicated and expensive laboratory process is often acceptable for producing gram scale quantities of a chemical product. However, it may not be a scalable basis for commercial manufacturing. Instead, process modifications and raw material alternatives usually need to be evaluated in great detail.

VC Funded Biotech Start-Up

A Chief Technical Officer (CTO) from a biotech start-up had an Investigational New Drug (IND) that had already been submitted to the FDA. There were several clinical trial candidates and the pre-clinical results were promising. However, the technical package contained vague data and there were no cGMP reference standards resulting in poor FDA compliance. They were up against the pressure of a critical timeline to save the project, and the potential for money to be lost and the project be abandoned was extreme when RCI became involved.

To address these issues, Richman Chemical completed a comprehensive evaluation of the technical package and identified the weak links. At RCI's direction, clinical trial batches were prepared with reference standards validation. Additional tests were performed for end formulation, concurrent with stability testing. A dialogue was established with therapeutic and delivery mechanism experts to ensure a product suitable for clinical trials. The result was a successful FDA review and a grant of fast track status.

Lesson learned: ETCs need to be forthright regarding information they share with selected outsourcing partners. If the outsourcing company knows the real problems, they have a chance to solve them.

“Ionic Liquids Development for Semiconductor Spin Off”

The client was in need of a key intermediate for a technology created on paper only. Because the client’s focus was keeping costs down, it wanted RCI to assume all risk in the project. Daily conference calls were also a requirement.

At first glance, these may seem reasonable requirements. In reality, however, when a project is going from “paper to lab”, the ensuing results can be unpredictable. Risk cannot be placed entirely on one player in such a relationship, as too many variables exist for both the customer and the manufacturer. And, while communication is key to the positive outcome of any project, daily conference calls take up valuable time and money that could otherwise be spent on the core project.

Richman Chemical educated the consumer as to the benefits of cooperative vs. adversarial relationships: specifically, risk cannot be placed on one side only when there are too many unknown variables. In addition, guidance from RCI’s project manager- who possessed extensive knowledge of the semiconductor market- helped to allay the client’s anxiety.

The result was a new technology developed for the customers 2nd generation product on a commercial scale and within the estimated timeline.

Lesson learned: Win-win always works! It is important to remember when outsourcing any project that the resulting arrangement must benefit- and be fair to- all parties.

“Biotech Start-Up with Scale-Up Challenges”

RCI was contacted by a virtual firm looking to custom synthesize preclinical and clinical batches of its proprietary API. The customer had an aggressive timeline and academia-based technology offering significant scale-up challenges. The company was also experiencing employee turnover--the head of manufacturing had been replaced twice within the previous 18 months. RCI’s project manager had the crucial skills to efficiently identify the technological challenges essential for project success and ultimately guide the customer through project development while its management team was reorganized internally. The project manager also proposed an alternative process technology to aid with scale-up issues. RCI even went a step further and devised a contingency plan in case the new processing technology did not progress as quickly as anticipated. As a result, the customer gained a team of expert project managers who had broad knowledge of drug development and access to a network of cost-effective resources. After initially working from a non-optimized process incompatible with scale-up objectives, the client was able to accelerate its commercialization timeline after the successful manufacture of its target API material.

Lesson Learned: There can be unseen benefits to outsourcing.

With over twenty-two years of experience, RCI is well known among emerging life science and biotech companies as a reputable provider of custom manufacturing, product sourcing and project management services. The firm helps its clients meet pharmaceutical and chemical outsourcing requirements and accelerate product development and commercialization. The company focus is on custom synthesis and processing solutions including cGMP, APIs, pharmaceutical intermediates, multi-step syntheses, metabolites and reference standards. While RCI specializes in full-scale synthetic production, it also has developed an extremely important niche with respect to unit operation capabilities such as toll distillation, custom drying, and particle size processing. Experienced chemical sourcing staff can locate difficult-to-find chemical compounds (any scale). Send your custom chemical inquiry to Christopher Kulp, Director- Contract Services Business, at clk@richmanchemical.com.