

■ ROUNDTABLE: OUTSOURCING

Why should a company outsource its research and development?



Tony Chilton, President & CEO, BASI

Perceptions and concerns about pharmaceutical companies outsourcing development of a future product are changing as the CRO/Pharma company relationship emerges to a partnership arrangement. It's a relationship where both companies are actively engaged in moving the product forward and meeting milestones. CROs have long recognized the opportunity to establish a working partnership arrangement with pharma customers. This has historically been achieved through strong project management and customer focus. Now this is being formalized in working partnerships.

Changes in the industry in recent years have allowed CROs to increase the scientific and regulatory and drug development experience by recruiting staff with long pharma experience. Now, the CRO provides a cost effective means of reaching a product milestone, but also offers the experience and scientific caliber of resources that were once part of the pharma companies.

In response to an industry shift in large pharma using smaller companies to identify and evaluate new therapeutic agents, many small/medium sized CROs are providing a broader base of services and expertise to help reach their milestones. Terms such as preferred provider programs that cover a series of experiments and projects that may take a new compound from late discovery through to IND are becoming more appealing.

As CRO's offer a more comprehensive and less commoditized service offering, the customer is gaining a very cost-effective

Kellie Malloy, Vice President & General Manager, Cardiovascular, Pain and Specialized Trials, PharmaNet

Pharmaceutical research and development is getting more complex. A pharmaceutical company's ability to adapt and be flexible is critical to ensure the highest quality research, allowing their products to be developed and brought to market in the safest, most efficient and shortest time possible. The CRO industry emerged to support the pharmaceutical industry in these efforts by providing them the opportunity to invest in scientific research while controlling control costs. Outsourcing provides pharmaceutical companies with additional flexibility along with an experienced available workforce to provide best practices across multiple therapeutic areas and geographies resulting in greater scalability and efficiency. When this is well done and managed effectively it can provide the best outcomes for all involved; especially the public by bringing safe and effective medications to them faster.



Michael McDowell, Director, Business Development, Lancaster Labs

To be successful in what continues to be a tight economy with ever-increasing pressure to advance multiple candidates with reduced timelines and resources, pharma and biopharm companies should leverage the well developed

capabilities and expertise available through contract service providers. Specifically, outsourcing saves time and money, broadens technical resources, and provides flexible capacity to achieve the next milestone or development goal. Here's why. Outsourcing enables companies to focus on their core competencies, freeing their staff for more timely multiple product development, oftentimes shortening their pipeline. Furthermore, the drug development process is anything but linear. Clients realize the inefficiencies of staffing to address peak work loads. Contract laboratories offer the timeliness and cost-effectiveness of flexible capacity. The combination of economic and performance pressure coupled with advances realized over the past decade in the contract services sector of the market make the reasons for outsourcing more apparent than ever. The only real question is which service provider can best meet my needs?



Gregory F. Krug, President, Lampire Biological Laboratories, Inc.

The marketplace is in a constant state of flux. The rate of change is accelerating and the direction for the medical device and pharmaceutical industries is being defined by cost control, political push toward "green", and regulatory agency policies in addition to the need for good science. If there was ever a time to "think outside the box" this is it. It is not realistic to expect a company to spend the time and dollars to re-invent the in-house R&D functions at the pace required to stay alive in today's markets.

Instead it can be more productive and efficient to go outside to companies, that are not hampered by the pre-existing "way we've always done it" corporate mindset. In the past, research was conducted by a single department or group per project with the expectation that they would use resources to identify how to move forward. I think this approach is too limiting.

We can't afford to let past practices limit our future achievements.