

■ BRAINSTORM

Is there a trend towards specialization or diversification amongst contract service providers? Are sponsors looking for a "one-stop shop" for all their needs?



Michael McDowell, Director, Business Development, Lancaster Labs

In theory, the "one-stop-shop," or identification of a single-service provider to support all of a sponsor's research and development needs is the preferred outsourcing model. In reality, it is extremely difficult to develop the breadth and depth

of technical expertise to do all things well. The company that tries to be all things to all people is often "the jack of all trades and the master of none." As the contract side of the pharm and biopharm industry has matured, providers have struck a balance between the need for specialization and their client's demand for diversification. For example, at Lancaster Laboratories we specialize in cGMP testing. We are the "one-stop-shop" for both pharm and biopharm companies looking for global capabilities to test everything needed for the CMC section of their regulatory submission. Put another way, if you need testing of starting materials, process or manufacturing testing support, or full characterization, release and stability testing of your drug substance and drug product, we're your lab. Yet we have been extremely disciplined. We have focused all of our resources: human, financial, and technical into being the best, most comprehensive QC testing laboratory in the world. It's the philosophy of doing one thing and doing it extremely well combined with the efficiency of a broad service offering in a specific area that is the cornerstone of Lancaster Laboratories' value proposition.

Joseph Miller, Director, Global Marketing, Norwich Pharmaceuticals

Many key providers within the CMO industry are clearly focusing business development strategies around the concept of specialized service offerings. This trend represents a shift from the general business approach seen in years' past where CMOs often were competing against each other to showcase the broadest possible range of capabilities. Shifting away from that approach is largely due to the more diverse range of innovative formulations and delivery systems now utilized by pharma companies. We have found that our customers value the ability to receive services for all stages of the product lifecycle from one contract provider, beginning with development and pilot production through commercial manufacturing. However, sponsors are now much more selective to identify single-source providers that focus capabilities on specific technologies and formulations rather than continuing to partner with broad, theoretical ranges of capability that often result in quality issues and delay on-time delivery.



Randall Guthrie, Vice-President, Xcelience

Our industry is going through a period of rapid change resulting in innovator companies of all sizes re-evaluating how they outsource. And yet, basic pharma



needs and outsourcing values remain fundamentally the same. Security of supply, price justification, and ease of doing business still rise to the top for provider selection. Speed may have taken on a greater significance in the recent economy, but not at the expense of quality, price and the service elements which have to be there. So, while pharma companies are under pressure to simplify their supplier base, it is also universally acknowledged that a one-stop shop cannot consistently meet all needs across all services equally well. I think the path forward is a portfolio approach that integrates the best of what the one-stop shop model can offer, combined with the advantages that only a specialized firm can deliver. There will always be room in a supplier portfolio for a specialized firm with a proven ability to reduce risk and accelerate drug development timelines, particularly if that firm integrates easily with upstream and downstream larger shop providers.