

# The future of the CRO industry

The pressures on Pharma/Biotech to control R&D costs while improving the yield of new, approvable drugs indicate an even greater reliance on outsourcing. So what will the next five years bring for the CRO industry?

Five years ago, as we approached the new millennium, the prevailing thinking among analysts and experts was that the Pharmaceutical/Biotech and Contract Research Organisation (CRO) industries were on the cusp of a revolutionary period in their respective histories. The mapping of the human genome and the advent of proteomics (and a slew of other 'omics' including metabolomics, pharmacogenomics, etc) led many to believe that the drug development process and the role of CROs therein were about to change fundamentally. The process itself was to become more efficient, delivering novel drugs faster while lowering the overall cost of discovery and development. And CROs were to play a key role in the integration and use of these new technologies. Pharma would begin to adopt a more strategic and holistic approach to outsourcing, similar to that of the information technology and automobile industries. Today, well into the first decade of that new millennium, most of these same pundits are lamenting the fact that neither industry has been transformed – yet they maintain that the drivers are still in place and the next five years hold the key to revolutionary change. Perhaps it is time for a realistic look at what the future could hold for CROs – as seen from the inside!

CROs have made significant inroads in terms of overall quality, scientific expertise and technical capabilities such that they are legitimate alternatives to in-house staff/resources, even for fully-integrated Pharma companies. Outsourcing shouldn't be, and increasingly isn't, used only when capacity is an issue. Many CROs have an experience base (in select

therapeutic areas, with specific technologies or logistics and execution) that is unmatched even among Big Pharma. That said, CROs seem to have fallen short of expectations in a few key areas that have hindered their ability to develop deeper, longer-lasting relationships with sponsor companies.

Contract research is essentially a service industry yet surveys repeatedly show that sponsor companies have mixed feelings about the level of service they receive. Communication channels can be complex, with multiple points of contact for a single project, and despite marketing claims to the contrary, timely communication of project status and results is spotty and inconsistent – not only from one CRO to another, but from one project to another within the same CRO. The advent of the 'one-stop-shop' was supposed to simplify both the purchasing and management of contract services, but CROs have been largely unable to sell the Pharma industry on the benefits of putting all their eggs in one basket. Why? Pharma companies still retain a portfolio of 'preferred vendors' (albeit one that is smaller than it was

**By Gilbert Godin**



## Business



in the 1980s or 1990s) who tend to be judged on the merits of their performance on the last project. There have been scant few deals between Pharma and CROs that have been truly revolutionary and/or partner-oriented. This lack seems to imply that the CRO industry is still considered transactional in nature and is not characterised by any particularly deep or collaborative relationships with sponsors. Due to their lack of infrastructure, Biotechs have generally been somewhat more accepting of CROs, but they too use the 'preferred vendor approach' when it comes to choosing which CROs to work with and often cherry pick best (or cheapest) in class when outsourcing.

So what do the next three to five years hold for CROs? How will issues like personalised medicine, biomarkers, Pharma's growing reliance on in-licensing, pharmacogenomics and imaging affect the services they provide – or will they affect them at all? Firstly, it is unlikely that the drug development industry and process will change in any radical fashion within the next three to five years. Because of the many variables and issues (scientific and regulatory) that need to be worked out (one of which has at least been clarified recently with the FDA guidance document on pharmacogenomics), the changes heralded by the 'omics' revolution (as characterised by personalised medicine) will likely be incremental rather than transformational as some experts have predicted. Making large 'bets' on specific technology platforms is a very risky way of developing expertise in these new areas. CROs must be mindful of these technology advances and be prepared to mine the benefits of

proven approaches. And this must be done without either destroying the CRO's current infrastructure or mortgaging its future by investing in any and all related technologies. One approach to ensure that clients have access to the latest discovery and development technologies is to weave together a number of world-class providers of different technologies under one service offering. MDS Pharma Services has taken the lead in this regard by establishing The Biomarker Alliance™, an alliance of the leading providers of genomic (Gentris), proteomic (Caprion), imaging (Massachusetts General Hospital) and clinical/bioanalytical (MDS Pharma Services) services and technologies. Clients are now able to easily access these services through one point-of-entry.

Secondly, CROs must get the 'service' aspect of their business right. They have proven that they can deliver a quality product, now they must convince the client (through actions, not words) that they can do it consistently. Certain cell phone companies have acknowledged this same issue of consistency and have made the strength and consistency of their signal (across the country) a key differentiating feature of their product. Consistency in the CRO industry service starts with the staff. This means that they must focus on developing an environment that allows staff to develop personally and professionally, reducing the high turnover that has plagued particularly the clinical research side of the business. Clients will reward such consistency with increased loyalty and, ultimately, a willingness to develop closer, deeper and more strategic relationships.

Lastly, once they address the 'service' issue

mentioned above, CROs need to find ways to develop and solidify more strategic (ie, deep and long-lasting) relationships with sponsors (notably Pharma). In order to accomplish this they will have to engage senior executives within Pharma and Biotech. These are the people who have the appropriate holistic view of the R&D process within their respective companies and understand the value/benefits that a more strategic, broad-based approach to outsourcing can bring – particularly to a company that is vertically integrated. If sponsors feel comfortable that their chosen strategic CRO partner is capable of delivering on its promise of performance – routinely and consistently – they will invest the time required to define, negotiate and develop a close strategic relationship.

While CROs may have fallen short of certain expectations, the industry has nonetheless experienced strong growth and is poised for even better performance moving forward. Having made significant strides in the areas of quality and scientific expertise, CROs have legitimately established themselves as a) alternatives to Pharma's internal resources, and b) expert drug development resources for Biotechs that have (rightfully so) little internal infrastructure. Pressure on the Pharma and Biotech industries to control R&D costs while improving the yield of new, approvable drugs points to an even greater reliance on outsourcing. Overall, industry growth rates should remain strong. However, those CROs that embrace their role as 'service providers' and take concrete steps to improve the consistency of the delivery of their

service will be in the best position to forge stronger and more strategic ties with their sponsors – and capture a greater share of the industry's growth. Success moving forward will not be measured by how many services a CRO can deliver, but by how well it delivers the services it offers and by how well these services can be integrated across the continuum of drug discovery and development needs of its clients.

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*Gilbert Godin has been President and CEO of MDS Pharma Services since November 2004. He joined MDS Pharma Services in 1999 as Vice-President and General Manager of its recently acquired Neo-Pharm business, and was promoted to Vice-President of the MDS Pharma Services Strategic Planning and Development group the following year. In 2001 he became Group Vice-President for the Early Clinical Research and Bioanalytical business units before being named Group Vice-President for all of Early Stage Development in 2003. His pharmaceutical industry experience includes nearly a decade at Schering-Plough, first as Director of Plant Operations at Schering Canada before transferring to Schering-Plough France as Director of Marketing and Sales for Urology and Infectious Diseases and then Director of the Viral Hepatitis Therapeutic business unit. A native of Montreal, Mr Godin studied pure and applied sciences at Collège Jean-de-Brébeuf and received a Bachelor's degree in Engineering from Sherbrooke University. He also holds an MBA from Concordia University.*

