

**S**ince the contract research industry has evolved largely as an extension of big pharma's internal R&D infrastructure, it was perhaps inevitable that it would come to be dominated by a few global companies. These CROs offer broad therapeutic expertise, the resources to conduct projects and trials in many countries, and the ability to carry out all aspects of product development from non-clinical toxicology and manufacturing through to regulatory approval and beyond. Surely, this has resulted in strong relationships between the major CROs and their pharma clients, as the former provides a 'one-stop shop' of pharmaceutical services at a reasonable price and consistent quality. What project director could ever be criticised for contracting work to one of these CROs?

Yet the evidence belies this assumption. A survey on CRO quality conducted last year by CenterWatch, a US information services company for the clinical trials industry, found that it is the small and medium-sized CROs that are now deemed more responsive, more accessible and less bureaucratic. And that the largest players are slipping down the rankings of preferred CROs. The largest, Quintiles, for example, held third position in CenterWatch's 1999 survey and had slipped to seventh place in this one. Similarly, Paraxel, placed in fourth place three years ago, had dropped to sixth and Kendle, from fifth to ninth position.

### **New challenges**

Although the pharma industry has yet to face the kind of economic downturn that has affected other R&D-based manufacturing industries in the past three decades, there is change afoot, driven largely by the need to sustain shareholder value with an ever dwindling supply of financial 'blockbusters'. Pharma executives are looking at their R&D process to deliver success, only to find it loaded with expensive failures, inefficiencies and increasing regulatory hurdles. While strides are being made to address these issues and reduce both the time and cost of R&D, change is difficult to effect in large organisations where progress can better be called evolution rather than revolution.

Contrast this with the automotive and aerospace industries. They took a sharp decline in their economic fortunes in the 1970s and 1980s before introducing radical new thinking into how they conducted their businesses. Their most important change was to recognise that survival came through understanding what they did best internally and what was best outsourced to

# Looking to the next generation of CROs

*Pharmaceutical outsourcing was valued at around US\$30 billion in 1999 and looks set to surpass US\$40 billion by 2004. But are existing CROs able to meet the needs of this expanding market? Dr Michael Bowden and Steve Mackenzie-Lawrie consider the challenges of the next decade*

a network of expert suppliers. It was their management of outsourcing that made these industries more able to cope with the demands of the new economic age.

There are no similar economic conditions facing the pharma industry, yet there is a detectable sense of urgency that change must be wrought in how the R&D process is managed, led in many ways by the small- to medium-sized companies and the biotechnology organisations for whom time and cost are fundamentally more important factors. As these companies look to their CROs to assist in implementing change, what do they see?

There is no doubt that the globally integrated CROs offer distinct capabilities based on their breadth of therapeutic and scientific expertise, their project management capability, and experience of conducting projects in many countries and with many regulatory authorities. They now employ thousands of staff and in some cases are themselves trying to become owners of products as well as suppliers of services.

But, all too commonly, one hears about the downside of being such a large organisation – lack of flexibility, variable quality of staff, poor communication, inefficient and bureaucratic internal processes, reluctance to adapt to change and high costs. Large organisations, no matter what their ilk, cannot easily control factors such as communication, flexibility and consistency in delivering a quality service. It was these kind of factors that the CenterWatch survey found were important. The ability to build good relationships, for example, was found to be a key feature in boosting the ratings of many of the small and medium-sized CROs. Indeed, 41% of the sponsor companies that responded said they expect to use smaller or niche CRO services more frequently in the coming years. A similar

percentage of sponsors said they would use a combination of niche and large full-service CROs. Less than one in five sponsors (18%) reported that they plan to use large, full-service CROs more frequently.

The problems that come with sheer size have long been faced by customers and suppliers in other industries. Aerospace, for example, has been at the cutting edge of using outsourcing to reshape its business for the past few years. In these industries, it is the business mission of the top service providers to develop the people, process and technologies to deliver at least the same, and usually higher, quality services at lower cost than their customers could achieve on their own. In these industries there is a realisation that no organisation, regardless of size, can hope to be best-in-world in every aspect of its operations; yet, none can afford to be anything less. The solution, built up over many years, is that customer organisations surround themselves with a network of specialised providers who are themselves best-in-world at what they do. Cost savings of 15-20% are common with similar increases in quality and throughput. Customers demand, and are given, focus, speed and constant innovation from their suppliers.

Does this sound like the situation in pharma? It is true that pharma companies are demanding more from their CROs. The question is can the CROs deliver? The answer is a cautious yes. Although it is easy to criticise the large CROs, on this point at least, they are trying to change. The problem of recruiting, training and, more importantly, retaining good people has at last been recognised; better processes to manage projects are being devised and implemented; and lastly, technology in the guise of electronic data management, the Internet and knowledge management systems are gradually being



designed and implemented. The niche CRO can also introduce a culture of continuous improvement and benefit from being at the forefront of technological change, particularly with electronic data management and clinical trial systems. Their ability to rapidly incorporate new initiatives and technologies is a function of their smaller size and one which larger organisations cannot replicate.

Thus, by combining people, processes and technology, smaller CROs offer significant competition to their larger brethren in being able to provide rapid access to high quality data, information and knowledge about their client's product.

Yet, niche CROs, for so long as they remain just that, will lack the global reach of larger CROs. Their biggest challenge, therefore, is to retain a high quality of service and constant innovation while achieving sufficient mass to offer global capabilities. But there is a solution

being used by other industries – supplier networks. Already one can see the emergence of the 'virtual' R&D organisation, the sole core competence of which is its strategic product development expertise and an ability to meld together many specialist suppliers into one R&D team. However, such organisations are entirely dependent on the ability of their suppliers and one weak link in the chain can prove disastrous.

To overcome this, the small CROs are starting to operate networks of suppliers while retaining the ability to deliver core skills at an operational level within their own organisation. Thus, in order to execute a multinational clinical trial, the small CRO may partner with CROs in countries in which it does not have a base to deliver site management and monitoring services while retaining the ability to lead and manage the overall project from within its own structure and by using its technologies to ensure effective communication, data management and quality. This then, is the next generation CRO – one that benefits from a smaller internal infrastructure while still being able to manage its own suppliers to deliver global services.

In other industries organisations are

finding that no single supplier relationship can be used to develop entire outsourcing strategies. For example, the world's number one shoe company, Nike, outsources all its manufacturing, preferring to retain core competencies in design and marketing. Nike utilises a three-tier partner strategy involving development partners, volume producers and the search for new suppliers. The first tier includes those suppliers working with Nike on co-development and co-investment strategies and with whom Nike wants to push out the boundaries of its product development process. The second tier uses vertically integrated suppliers who manufacture high volumes of mature products. The third tier consists of new suppliers whom Nike believes have the potential to become one of the other two tiers and with whom they work and influence to that effect.

### Niche CROs lead the way

In pharma R&D it is possible that a similar approach may emerge in the next decade. Niche CROs will be the equivalent of the first tier in Nike's model offering the pharma industry a constant source of innovation, flexible delivery of services and rapid product screening. The second tier will involve the larger CROs that are able to conduct global trials and manage large volumes of information.

But underpinning all future pharma outsourcing will be a shift away from purchasing 'volume' and 'capacity' in the sense of how many monitors a company may have, towards purchasing 'solutions' in terms of how can 600 patients be recruited within a six-month timeframe?

In making this shift many other factors will change. Pharma companies will become more sophisticated in how they purchase services, encouraging service performance via new 'shared destiny' contracts, and the attainment of a new relationship based on partnership and mutual respect.

In conclusion, the globally integrated CRO is neither a dinosaur nor about to become extinct. But it is about to undergo significant change driven by challenges from the small, next generation CROs which, for the first time, are able to offer all the advantages of global reach with none of the disadvantages emanating from their small size. SM

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Size matters when it comes to contracting out. Small niche CROs are predicted to increase their share of pharma business.

introduced. Yet the pace of change is slow and it is this that is providing the ideal opportunity for niche CROs to become important players in the new outsourcing market.

The globally integrated CRO is not yet a dinosaur about to become extinct, but it may become endangered if it does not compete with an increasing number of small niche competitors that are fleeter of foot – the next generation of CRO.

### The next generation

There have always been small CROs. What has changed in recent years is their ability to carve out recognised niches, recruit good staff, and leverage technology. In an increasingly knowledge-based industry, experienced people are looking for a varied, multi-tasking environment in which to gain expertise or bring to bear their accumulated experience unfettered by departmental silos and bureaucracy. This is exactly the environment created by niche CROs and the mutual fit is proved by the steady flow of talent away from larger organisations. This allows the smaller CRO to offer its clients a good deal of strategic as well as operational expertise and, in some cases, entire development strategy is being