

R&D outsourcing

Carefully selected external service providers can be cost-effective and relieve the pressure on firms looking to streamline operations

With all of the demands on pharmaceutical companies today to be more efficient and compliant with regulations, research and development (R&D) organisations are choosing to use external service providers increasingly to help relieve the burden.

Where once drug companies might have been reluctant to entrust intricate processes to an outsourced service provider, attitudes are changing. Not only do firms need to offload tasks so that they can allocate internal resources more prudently, but the range, scope and quality of external services are also becoming more sophisticated.

The result is that companies are becoming bolder in what they outsource and how they do it, according to the 2010 Business Insights report, *The Future of R&D Outsourcing*.

The reasons for outsourcing are common to many pharma R&D organisations and include cost containment, standardised systems and processes, staff augmentation and geographic spread.

The potential savings via outsourcing are sizeable. Slimmed-down companies can no longer justify having large staff pools to manage work that could be done more efficiently and more effectively by a specialist service provider with superior economies of scale and the capacity to scale up its activities to handle peaks in the workload.

Increasingly, such partners can be found in emerging markets, such as India and China, which have high numbers of science professionals, making them attractive and cost-effective bases for managed services. Offshore outsourcing to those countries offers potential cost savings of 30 to 60 per cent, according to the Business Insights report.

Given that companies do not always have a regulatory presence in every region in which they do business, a single partner that can manage activities across multiple markets is an attractive proposition.

Standardisation of systems and processes is helping to make outsourcing more feasible, certainly. Electronic submissions, for example, allow for greater consistency and streamlining in the ways processes and documents are handled across geographies, thereby bringing down boundaries.

What to offload

As companies gain confidence in external services and as their need to streamline internal operations intensifies, the accepted norms of outsourcing are changing. Activities once considered too precious are now being let go, because the potential benefits are seen to outweigh any risks companies had once imagined. For example, it is now possible to let an external provider put together an entire New Drug Application on a company's behalf. This is something that would have been unthinkable a few years ago.

How much to outsource

The outsourcing of entire business processes is a growing trend, according to Business Insights, provided that the selected activities are repeatable and consistent. In the regulatory domain, this has become increasingly the case following the introduction of

electronic submission standards.

The quest for transformation through innovative new approaches and processes is another growing theme. If innovation is a determinant in the outsourcing relationship, however, this must be made clear from the outset. The main priority here is to select a partner with an organisational structure centred on innovation. Since most outsourcing services are built to deliver cost efficiencies and standardisation, it is advisable to look for a 70/30 ratio, whereby 70 per cent of the work is handled through standardised processes and 30 per cent is customised.

Going offshore

The opportunities for cost savings and geographic spread make offshore outsourcing attractive, but many companies remain cautious about how much and what they are prepared to send offshore. Concerns tend to centre around legal wrangles and the quality of the work being done, language barriers (for example, in medical writing), and potential process challenges that might arise from working across geographies with external partners.

However, China in particular is becoming a more reliable end destination for certain critical functions. Increasingly, pharma companies are recognising that the opportunities presented by a market such as China far outweigh the risks, especially when the processes are well managed and the partnerships carefully selected.

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→ Selecting a partner

As confidence in outsourcing grows, organisations need to develop more refined strategies for initiating and managing such critical partnerships to ensure that the benefits are realised. Selecting partners on price alone is doomed to failure. Business Insights found that 35 to 55 per cent of project sponsors were dissatisfied with the results, which can be attributed largely to a poor selection process.

Happily, there is greater acceptance now that the solution must fit departmental needs rather than the other way around. A growing maturity on the part of the client organisation means that companies are now entering outsourcing negotiations with a clearer sense of what they need. For their part, supplier organisations are now more in tune with their clients' requirements, too, thanks to the experience they have gained from the multiple clients with which they work.

Knowledge or expertise, along with the company's flexibility, its people and its budget, are among the main decision criteria companies invoke when choosing a partner, according to Business Insights. The vendor's communication capabilities and ability to foresee issues and respond to them are widely deemed important, too.

Establishing synergy

The emphasis of any outsourcing engagement should be on the long-term success of both partners. This can be achieved only when the relationship is strong and built on trust, based on the client and vendor having shared values and beliefs. The outsourcing partner should become an important collaborator in the process, but companies must still retain their own knowledge and capabilities.

When one global pharma company began considering outsourcing options in regulatory operations, it started by establishing a small group in China to test the environment and then turned to an outsourcing partner there to handle overspill work. That synergistic relationship has been shown to work well for that company because it has broad oversight but shifts large amounts of document processing to its partner.

What is particularly valuable about that relationship is the 24-hour capability it offers because, in addition to turning to its partner in China, the company has publishing capabilities in both the US and the UK. Even though it took time to smooth the processes, this outsourcing relationship has been advantageous because it has forced the company to standardise its methods, resulting in better quality and uninterrupted workflow.

The outsourcing of items that were handled in-house before also changes them from fixed costs to variable costs, which leads to financial savings in the longer term.

In the regulatory arena, outsourcing to a trusted partner can ensure rapid turnaround on the large, critical projects that companies often encounter. For example, a company had two weeks to complete a large submission to the US Food and Drug Administration but did not have the resources to manage it. Instead, the company turned to an outsourcing partner with offshore capabilities. The vendor was able to draw on its staff in the US and Asia, applying 800 hours to the job, with the result that the submission was completed with a week to spare.

At times like that the real value of using external support becomes evident. Such pressures are likely to increase rather than wane, too. The drive to cut costs, meet shareholder demands, bring products to market more rapidly and improve product pipelines means outsourcing is likely to become an increasingly important part of R&D business. Making it work just requires good planning.



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Biosimilars and the FDA

The US Food and Drug Administration (FDA) is seeking written comments from the biotech industry and other stakeholders on its efforts to develop a user fee programme for biosimilars, which are defined as biological products that are demonstrated to be highly similar to, or interchangeable with, an FDA-licensed biological product.

User fees, which are already in effect for drugs and biologics, are fees from companies that are used to expedite the process of reviewing marketing applications. The FDA's efforts on developing a user fee system for biosimilars are based on the Biologics Price Competition and Innovation (BPCI) Act of 2009, the legislation that is intended to create a regulatory pathway for abbreviated approvals of generic biological products.

The BPCI Act, which is part of the healthcare reform package that was signed into law by President Barack Obama in 2010, will create a shorter approval pathway for biosimilars along the lines of the application process that exists for generic drugs, which allows generic manufacturers to rely on data that has already been gathered about a drug, rather than duplicating trials. The BPCI Act is similar to the 1984 Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, which focused on expediting the approval of generic drugs.

Since the passage of the BPCI Act, The Biosimilar Implementation Committee (co-chaired by Dr Janet Woodcock, director of the FDA's Center for Drug Research and Evaluation and Dr Karen Midthun, acting director of the FDA's Center for Biologics Evaluation and Research) has been working to implement the new pathway. BPCI directs the FDA to develop recommendations for a biosimilars user fee programme for the fiscal years 2013 through to 2017. The recommendations must be presented to Congress by January 15, 2012.

The FDA said that, in addition to reviewing the written comments on the user fee issue, it would consult with a range of groups, including scientific and academic experts, healthcare professionals, representatives of patient and consumer advocacy groups, as well as regulated industry. It would then develop proposed recommendations that would be published for public comment, presented to Congressional committee staff, and presented at a public meeting.



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