

Outsourcing Strategies: from David to Goliath

The role of outsourcing is necessarily different depending on the size of the client. Leslie Patmore and Peter Gaskin at Aptuit Consulting offer their advice for both big and small companies alike



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Peter Gaskin holds BSc and PhD degrees in Biochemistry and Toxicology, and has worked in pharmaceutical R&D for over 18 years. He began his career working in regulatory and investigative toxicology at ICI's Central Toxicology Laboratory, followed by a number of posts in research and regulatory toxicology in the pharma and CRO industries after completing his PhD. In 1999, Peter joined Quintiles, firstly as a Program Manager and subsequently as Associate Director and Head of Program Management. In 2005, Peter was appointed a Principal at Aptuit Consulting. He is a member of the British and European Toxicology Societies and a member of TOPRA.

Outsourcing by pharma and biotech is growing at a rate of 14-15 per cent per year. Representing around 25 per cent of R&D spend, and an even larger proportion of development costs, outsourcing was estimated at US\$14 billion in 2005 and is estimated to reach \$20 billion by 2010 (1). These increases are being driven by a number of factors, including the growth of the global economy, increasing demands of regulatory guidelines, changing business models (for example, the growth of small/virtual biotechs with little or no in-house development capability), and reduction of in-house costs by larger pharma companies (see Figure 1).

Why do companies outsource? They do it because it's cost effective and successful. A recent study by Tufts found that projects are completed more quickly by sponsors who outsource a large amount of work to CROs and maintain levels of quality compared with submissions made without extensive use of CROs (1). They found projects involving a substantial amount of outsourcing reach regulatory submissions more than 30 days earlier. The benefit of bringing a product to market faster is the overwhelming driver, but for leaner pharma and biotech R&D organisations, outsourcing decreases fixed overhead costs.

OUTSOURCING MODELS

The key to outsourcing effectively is to understand that different organisations require different things. Deciding on your company's outsourcing strategy will depend on a number of key points.

Commercial Strategy

Drug development is an extremely complex, costly and time-consuming process. Very few companies are large enough or want to perform all of the tasks required and companies therefore need to make strategic decisions on what tasks to outsource. The strategy may simply be a drive to keep fixed costs low; it may represent a desire to focus internal resources on a key project, whilst ensuring that other projects progress with less demand on key staff; or it may be that certain tasks can be performed more cheaply by service providers. The commercial strategy should be the starting point for all further considerations regarding outsourcing.

Type of Work Required

Quite simply, if the work has to be conducted by GLP or GCP, and your facility and staff are not covered by a GxP compliance scheme, you have two choices: either outsource or develop

SOPs and train staff to obtain GxP compliance. Specialist techniques are better left to the specialists. In some cases, this may be your staff, in some cases specialist providers, and in some cases academia. Each need to be managed differently, and expectations of output and timescales should be adjusted according to where the work is being done.

Physical Resources

What is the capacity of your organisation to do the work itself? Can you do the work in-house in the timescales required? Are the physical resources, including equipment and space, available when the work is required to be conducted? Are they best used to conduct the work in question, or would they be better utilised to support other projects? Would the best commercial strategy be to wait until internal resources are available to conduct the project?

Expertise

The need to outsource will depend on whether the right individuals with the correct skill sets and level of expertise are available in-house. An assessment of the experience and training needed to conduct the work to the standard required by the relevant guidelines should be compared with those of key individuals within your organisation. When making the assessment, don't overlook the experience and capacity of the staff who would be involved in managing outsourced work. Do those managing the outsourcing of work have the time required to manage the project effectively? Do they have the appropriate level of training in project management and experience of dealing with outsourced work and contractors?

Geographical Location

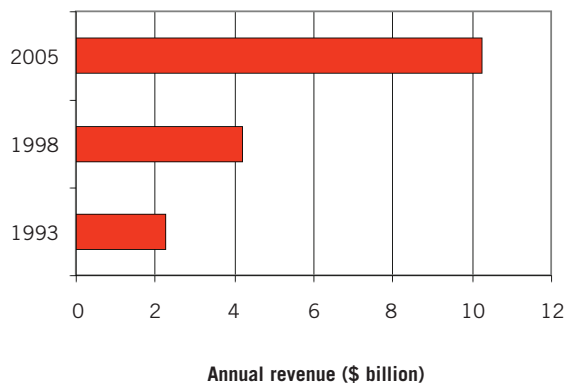
Consideration should be given to the location of the service provider relative to the person managing the project within your organisation. Unless it's only a small project, a project manager should be employed to oversee the work and deal with any immediate issues if the work is conducted away from where your company is based. Some companies will require high level strategic advice from a consultant or project director; others will require someone who can deal with day-to-day issues, but may not have the experience to provide strategic advice or solutions to challenging issues.

INTERNAL COST OF OUTSOURCING

Outsourcing solves the problem of availability of internal resources to conduct the required work, but it is not without internal cost. This can be a critical underestimate made in the outsourcing process. Without doubt, the more attention paid to outsourced projects, the better the result, whether this is to do with provider selection, contracts or management and interactions with the service provider. Poor CRO performance can sometimes be associated with a lack of attention from the

Figure 1: Increases in outsourcing (in dollars) 1993-2005

Outsourced work from pharma and biotech increasing between 1993 and 2005. In 2005 this represented 25 per cent of the total global R&D spend (2).



outsourcer. This is quite easily understood, since lack of internal resources and time was a driver to take the work outside. Assigning enough time and resources to thoroughly manage and monitor this process is therefore critical for successful outsourcing.

PROJECT MANAGEMENT

The way an outsourced project is managed has an impact on its overall success and time to completion. Within the umbrella of 'project management', different levels of leadership, management and administration are applied. For a successful outsourcing project to be completed, the right mix of these activities must be delivered to suit the project and the contracting environment.

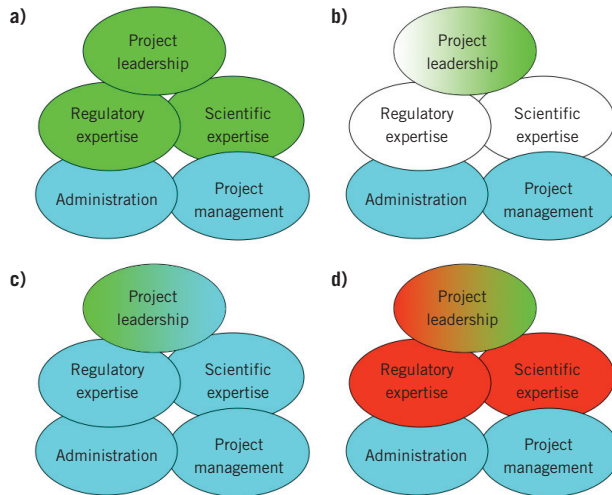
Depending on the type of work being conducted, the CRO or CMO may provide a project manager, or in some cases merely identify a lead scientist who is the point of contact. For GLP studies, a study director may be the point of contact. The resources being assigned by the service provider dictate the level of management that will be required by the sponsor. Different models for these activities are shown in Figure 2 (see page 10).

It would be reasonable to assume that the management and administration of a project should be well covered between the two parties. Of more overall importance will be the scientific leadership and oversight of the work to be conducted, as highlighted in the model. One of the drivers for outsourcing is where the sponsor either does not have the resources to conduct the work or does not have sufficient knowledge of the regulatory or technical area. In both of these cases, there is likely to be a requirement for the provider to fill this gap; therefore they should be expert in the discipline and able to provide scientific leadership regarding strategy, study design and data interpretation. Anything less and there are possibilities that the contracted work will not be adequate to address the issue or meet regulatory requirements; this in an environment where the sponsor can be oblivious to this shortfall. Ensuring

Figure 2: Models for provision of expertise and services

There are various models for providing expertise and management and leadership services for the successful completion of outsourced projects: **a)** the sponsor provides scientific and regulatory expertise and overall leadership; **b)** where scientific and regulatory expertise is lacking, the sponsor can provide incomplete leadership; **c)** the service provider delivers scientific, regulatory and project management services as well as providing technical capabilities/resources, enabling non-expert sponsors to provide project leadership; and **d)** consultants provide scientific, regulatory expertise and partner with a non-expert sponsor to provide overall leadership.

Key: ● Sponsor ● CRO/CMO ● Consultants



BESPOKE OUTSOURCING SOLUTIONS

We've looked at the key elements used to define outsourcing strategy and other points to consider regarding management of outsourced work, but how do outsourcing strategies differ for different organisations? Below are some examples which serve to illustrate a variety of outsourcing strategies employed by different types of organisations.

University Spin-Out

University spin-outs have very limited capabilities in-house and need to outsource the majority of work and particularly the key regulatory studies. The project lead will often have worked with the lead candidate and others in the series for some time, and will have an enviable in-depth knowledge of drug substance. Typically (but not always!) they will have limited development/regulatory experience. In our experience, there are an increasing number of individuals in academic organisations who are serial entrepreneurs and technology transfer units associated with universities can also lend useful commercial support to less experienced individuals.

that any gaps in the higher level aspects of outsourcing are met is essential (see Figure 2).

USE OF CONSULTANTS OR PROFESSIONAL PROJECT MANAGERS

Who can provide the project leadership or scientific expert role?
This falls to two groups of professionals:

- ◆ Experienced drug development project managers and a number of consultants or in some examples with one consultant fulfilling several roles
- ◆ The expert (in specific areas) providing leadership in the overall development of the product and providing project management

Where these independent contractors are used, the opportunity to have them manage several different providers who are needed to contribute to the model is an added benefit.

With an individual project lead or a very small team, relationships and the communication plan will be key to ensuring the project lead is not swamped by demands for information from the service providers. Working with a small number of service providers, delivering a full service offering is likely to be a good strategy, with competent project management essential. Support from an experienced and trusted consultant can ensure that the early development strategy is sound and that the project is managed effectively and in a timely manner. In such cases, the consultant also helps by guiding the project lead to deal with the most important issues, whilst resolving more pressing, but less important issues.

Virtual Biotech

As with the university spin-out, virtual biotechs have limited in-house resources, and the project will be managed by a small team. Unlike the university spin-out, the virtual biotech development team members are likely to have

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commercial experience in drug development and in contractual issues. The combination of a small team and development expertise means that the number of suppliers should be kept to a minimum. Unlike the university spin-out team, however, members are likely to be sufficiently experienced in their area of responsibility to work independently with different service providers specialising in their discipline. We have often found that this division of responsibility is successful where individuals are sufficiently experienced in their chosen field, and a good communication plan is in place to ensure that the different aspects of the project integrate effectively. Relationships with the service providers will once more be important. Consultants may be used to fill the gaps in the virtual development team to advise on strategy, manage sub-contractors and/or address arising issues.

Small Pharma/Mid-size Biotech

By this stage in an organisation's development, the staff will be used to outsourcing work, and the company will have more capacity in-house. The development team will be familiar with the key strengths of individual suppliers and will have already established relationships with key suppliers. Consequently, the development will resemble a jigsaw, with some pieces conducted in-house and specific areas outsourced. In our experience, the work outsourced will depend on a number of factors, including strength of capabilities and physical resources in-house, known areas of expertise of service providers and relationships with key individuals gained through work on earlier projects or in other organisations. As with the virtual biotech, consultants may be used to fill the gaps in the development team to provide advice on specific areas of strategy and/or to address arising issues. Consultants may also be employed in the role of project director to manage outsourced studies where multiple suppliers are used and management resource in-house is limited, or where studies are being conducted at a site removed from the in-house development team.

Blue Chip Pharma

The outsourcing model is quite different for large pharma. With a large throughput of studies and significant in-house capacity, large pharma are looking to place studies when their in-house capacity is exceeded, in niche areas. With increasing frequency, they are also interested in 'volume' deals and 'buying space'. Large pharma are likely to have sufficient resource in-house to develop strategy, design and manage outsourced studies, minimising the requirement for external high-level support. Our experience concurs with others that the trend with many large pharma is to increase levels of outsourcing and hence volume deals and buying space is likely to become more prevalent in the future. The rapid expansion of floor space and staffing levels of service providers, for example at preclinical facilities, is testament to the CRO industry gearing up to meet the increased demand.

VALUE ASSURED

When trying to get the best value from outsourcing, remember to:

- ◆ Ensure sufficient resource and skills in house to manage outsourced work
- ◆ Ensure that there is the right level of scientific leadership and project management employed either in-house, provided by the CRO or CMO, or from consultants
- ◆ Be ready for conflicting advice and ensure that you provide advisors with as much information as possible to ensure that you get the best advice from them
- ◆ Select the right vendor based on the considerations above. Track record of quality and delivery of services, and price. Where there are potentially multiple service providers and availability, price can be negotiable, but driving down price will influence service provider margins. Ultimately, this results in cost and service cutting and is not necessarily the best route to ensuring quality delivery or developing a long-term partnership
- ◆ Develop and maintain good communication between the players in the extended project team

CONCLUSION

Outsourcing continues to grow and the practice of outsourcing is becoming more refined as volume increases, the associated costs have more financial impact on R&D budgets, and the sector matures. Growth in medium and large pharma outsourcing groups has been seen over recent years, but as new companies emerge there still remains a lack of experience in the practice of outsourcing. Successful outsourcing is based on ensuring that the right scientific, management and technical resources are applied; getting the mix right will realise the benefits of more rapid drug development and cost saving. ◆

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