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Supporting critical Phase I–IV clinical studies by outsourcing supporting elements

What are the outsourcing trends and challenges facing the pharmaceutical industry when looking to outsource difficult services such as bioanalysis? Critical factors for identifying the ideal outsourcing partner and building an accretive and rewarding relationship are considered.

Mar 01, 2008
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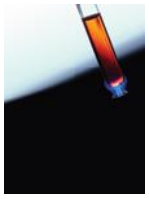
Pharmaceutical Technology Europe



The pharmaceutical industry has experienced a number of difficulties during recent years. Greater competition from generics (more than 60% of prescription drugs are supplied from the generic market) and increased gaps in the drug pipeline that result in acquisitions or strategic alliances has led to a feeling of uncertainty in the bio/pharma marketplace. There have also been changes in the marketplace with a shift from primary care to specialty drugs, the introduction of personalized medicine driving the need for biomarker/diagnostic technology and the introduction of biopharmaceuticals.

With the pressures of time-to-market, the associated costs of discovery, the attrition rate from generics, and patent expiry and development in pharmaceutical products, pharmaceutical companies are increasing their investment in off-shoring and outsourcing. Whether this is strategic or tactical, the contract research organizations (CROs) need to be pro-active in responding to their sponsor's requirements for cost-effective services; for example, by offering a breadth of services, an innovative approach and a commitment to the sponsor in terms of understanding and risk sharing.

As industry constantly strives to cut development times, maintain quality, reduce development costs and boost productivity, there has been an increase in outsourcing spend. Since 2001, the pharmaceutical industry has upped its financial commitment to contract clinical services by 16% annually to $6.6 billion (€4.45 billion),[1] which is greater than the annual rate of growth in overall development spend (11%).

Outsourcing falls into two categories:

> Strategic outsourcing allows a pharmaceutical organization to focus on its partners' core strengths and long-term goals. It enables the sponsor to maximize the vendor's internal resources and capacities, thereby adding value to the product development process. This route provides a flexible service model. As an example, pharmaceutical companies will estimate their required capacity for a period of 3–5 years, reviewing how they can utilize key talent, resources and equipment from a CRO partner supporting, for example, low-risk projects, allowing more productive use of internal resource.
> Tactical outsourcing relates to short-term projects that cannot be handled internally because of the lack of capacity or resources. This route allows for streamlined processes, fast turn around times, access to additional equipment and so on. One example is outsourcing to peaks and troughs in work on a project by project basis, such as ICH product method revalidations.

The pharma head count has remained static and current challenges have altered the dynamics of the market, which has a focused on R&D performance and strategy. With the influx of small and medium-sized biotech enterprises, pharmaceutical organizations have become reliant on CROs for a full service infrastructure, experience and greater efficiencies to support Phase I–IV studies. The problem of choosing the right outsourcing partner has been exacerbated by the recent growth in the number of CROs entering the market. Often these organizations appear to offer similar services and returns for the customer, which makes the partnering decision difficult.

The majority of companies are moving from tactical to strategic outsourcing and are looking to develop partnerships with CROs. Before entering into such an agreement, an initial assessment of the CRO should be made. Important factors to consider include:

> The right corporate culture.
> A cost-effective structure.
> Sufficient and relevant technology, including software infrastructure.
> Flexible human resources.

These factors, combined with effective communication, provide the basis of a good CRO/pharma partnership.

Bioanalytical outsourcing adds a further level of complexity in managing a CRO, but allows for added value such as rapid — but regulatory-compliant — method validation. The critical factors for identifying a bioanalytical partner are:

> Quality and regulatory compliance.
> Scale and flexibility in capacity, but also in understanding potential delays and variations in projects.
> Commitment to the project and associated risk — a clear understanding and shared vision promotes the growth of an excellent partnership.
> Costing versus confidence — technical expertise, a breadth of experience in method development, validation and clinical sample support is paramount.
> Communication — this should be a two-way process to help promote clear, up-to-date project status and to manage expectations.
> Key performance indicators. Projects vary in complexity, but performance and track record measuring processes, staff and the end result are key to understanding future project expectations.
> Contracts — clear goals and objectives established at the start of projects.
> Financial stability — ensuring your CRO partner is a reliable, long-term resource during lengthy studies.

Quality

Quality of work is paramount to bioanalytical studies, and is a measure of the systems in place within a CRO to facilitate timely delivery of high-quality data and reports. It is important to determine which quality systems a prospective CRO has in place:

- Are the vendor's quality systems adequate (standard operating procedures in place and good laboratory practice-accredited)?
- Inspect the quality process, and review procedures and peer-review steps.
- Are they adhering to the latest regulations?
- How long have they maintained accreditation?
- How much sponsor feedback have they received and how positive/negative is it?
- Do they have complete training records and an adequate training programme that gives them a technically astute resource for projects?

Commitment

With the time and financial commitment in planning and outsourcing clinical and supporting bioanalytical analysis, commitment between the sponsor and CRO promotes an effective partnership. Each project is individual and can vary in size, but implementing the following can enhance the partnership:

- A shared vision — planning and forecasting future workloads.
- A single point of contact within the CRO and continued project updates that ensure all parties are aware of changes in the projects and timelines.
- On-going quality assessment.
- Having a shared understanding of the risk and sharing the successful outcome of a project.
- Having a master services agreement in place and detailed contracts that allow the CRO to understand the exact requirements of the project from the outset.

Communication

A structured and disciplined approach to communication can deliver desired business benefits. This should include:

- Frequent face-to-face meetings.
- Effective kick-off meetings stating clear expectations, milestones and delivery targets.
- Clearly defined roles and responsibilities of the sponsor and CRO.
- Tools, templates and formal processes for documenting sponsors' expectations prior to the start of any project.
- A recognized format for feedback throughout the duration of a project, such as status reports or a project manager.
- Project review using key performance indicators/ratings to allow timely sharing of knowledge and information to reinforce the relationship/partnership.

Balancing cost and confidence

When faced with the prospect of outsourcing you must be convinced of the viability and robustness of your decision to hand over control of a project to a third party. As the project manager, you must also be confident about getting value for money, quality and delivery.

Cost is often a key factor, but is very rarely the most important. You will be reluctant to spend even a small amount of money if you are not confident in the CRO's ability to deliver on time and to the specified quality. Missing targets can be very costly to both the CRO and sponsor, and absorbs valuable time.

Indicators of good service provision are:

- Appropriate quality standards.
- CROs' understanding of sponsors expectations.
- Enthusiastic and helpful CRO analysts who inspire confidence that problems will be dealt with promptly and effectively.
- Knowledgeable and competent staff who receive continuous training.
- Staff involvement in improving their knowledge and competence through networking and becoming members of scientific groups.
- A robust training plan that includes both scientific and commercial development.

Protocols

Setting up contracts is occasionally a a contentious issue. As the project manager you may be unwilling to commit to a contractual agreement. There are advantages and disadvantages to contracts that need to be addressed.

The types of 'contract' required must be defined.

A confidentiality agreement protects against fraudulent use of your intellectual property. Most pharmaceutical companies have a standard template that can be quickly issued to a CRO on request.

A technical agreement details the nature of the testing and the manner in which both parties conduct business. It includes the official names and addresses of each company, and details of quality standards, for example. There should also be a template for this available within most organizations.

A financial agreement needs to be drawn up to define the payment schedules.

Often, the above can be seen as an obstructive series of hurdles delaying the start of the project, or additional work for the project manager. This need not be the case — a good CRO will make this process as smooth as possible by providing in-house templates and promptly signing and returning documents.

Similar to any business decision, there are many contributing factors in the process of choosing your laboratory partner. However, the above steps will aid selection.

Collectively, they indicate an organization's competence and, more importantly, their willingness to move that little bit further to ensure your project is a success. There will be regular dialogue between the CRO and yourself before, during and after the project so it is extremely important that you feel comfortable with the company and staff involved.

The key areas discussed in this article can be investigated in a relatively short time frame and can go a long way in giving you the confidence to commit company resources to an audit and, ultimately, a partnership.

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References

1. Contract Pharma, 2007 Outsourcing Services Report. www.contractpharma.com [2]

Links:
[1] http://www.pharmtech.com/vikki-renwick
[2] http://www.contractpharma.com/