Making the Right Choice

David Tudbury and Vikki Renwick at Tepnel Pharma Services look at the trends in pharmaceutical outsourcing and consider the key drivers for customers when choosing an outsourcing partner in today's challenging financial environment

Outsourcing of analysis within the pharmaceutical industry has steadily increased in recent years, but this trend has been challenged during 2009. There is large variability in predictions, meaning that against this uncertainty an ever-focused industry will need to ensure that it is getting the greatest value for its outsourced expenditure.

The variations in predictions can be seen in the *Contract Pharma Outsourcing Survey 2009* report, as well as reports from organisations such as BCC Research. Despite this variation in predictions, the fact remains that choosing the right outsourcing partner is a critical factor for future success. The key reasons for outsourcing analysis include:

- Little or no facilities in-house
- Bespoke services or knowledge
- Utilisation of internal resources on higher value return science that is the use of staff on core business activities
- In-house capacity problems due to increased testing to meet with regulatory requirements

The challenge of choosing the right outsourcing partner has been exacerbated by the growth in the number of contract service organisations (CSOs) in the market. Many of these organisations appear to have little to differentiate them, offering similar services and performance statistics for the customer, thus making that crucial choice that much more difficult. The key areas identified include: cost versus confidence; the ease of doing business; quality; cultural fit; and communication options. The analysis will focus on these key aspects when choosing the right partner.

BALANCING COST & CONFIDENCE

When faced with the prospect of outsourcing, organisations must be convinced of the viability and robustness of the decision to hand over control of a project to a third party. The project manager must be confident about getting value for money, quality and delivery from the outsourcing partner over the duration of the study.

Cost is often a key factor but is rarely the most important. Companies will be reluctant to part with even a small amount of money if they are not confident in the CSO's ability to deliver on time and to the right quality. Poor performance in achieving agreed targets can be very costly to both the company and to the individual, absorbing valuable time.

In today's environment, a review of as much financial information as is available is time spent wisely. Those without financial stability behind the organisation should be subject to further scrutiny, particularly if the decision is to place long-term activities supporting the drug development cycle. Indicators to good service provision are:

- Appropriate quality standards
- CSO analysts are enthusiastic and helpful, indicating that problems will be dealt with promptly and effectively
- Knowledge and competence of the staff
- Involvement of the staff in improving their knowledge and competence through networking and membership of scientific groups
- Presence of a robust training plan, which includes both scientific and commercial development
- Reliable and consistent metrics

Organisations must look beyond the sales staff and get exposure to the scientists to give businesses the confidence to commit resources and finance to any partnership. When making the final decision, a visit to the facilities is rarely a wasted trip.

EASE OF DOING BUSINESS – MANAGEMENT OF THE OUTSOURCING PROCESS THROUGH CONTRACTS (PROTOCOLS)

Setting up contracts can sometimes be seen as a contentious issue, and decision makers may be unwilling to commit their company in writing to a contractual agreement. There are advantages and disadvantages to contracts that need to be addressed. There is a need to define the types of 'contract' required:

1. A confidentiality agreement is needed to ensure protection from fraudulent use of intellectual property (IP). Most

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pharmaceutical companies have a standard template which can be quickly issued to a CSO on request. Do expect the agreement to be two-way as there is often IP that the CSO will be keen to protect.

2. A technical agreement detailing the nature of the testing and the way in which both parties will conduct business. Included in this are 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 organisations. This agreement can sometimes be combined to create the quality agreement. It is important to ensure that all agreements are available to the scientific staff by understanding the CSO's processes.

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

Often these contract types can be seen as a series of hurdles in the way of getting the work started and processing additional work for the project manager. This does not have to be the case; a good CSO should take the initiative and make this process as smooth as possible by providing in-house templates and signing and returning documents promptly.

There are obvious advantages to having a technical agreement in place before testing. Both parties know exactly what has been agreed from the onset. Details such as methodology, timescales and costs can be defined clearly.

The technical agreement is the most important document to the project manager. In some cases, it is a regulatory requirement that testing does not start until precise written instructions are given. Having a technical agreement in place ensures that both parties examine the project in detail before committing to a testing regime. The project manager cannot assume that the contract laboratory knows exactly what is involved in testing the product and, conversely, the professional CSO would not assume that they know all the implications of the testing.

A less obvious advantage of pre-analysis dialogue is the opportunity to get the most out of the CSO. It is an ideal opportunity to discuss technology transfer and review potential problem areas during testing. The project manager should be able to access the CSO's knowledge and past experiences in testing similar products.

The CSO should take the initiative in facilitating the contracts, thus minimising the customer's time and cost. The CSO must also adopt a sensible, pragmatic approach and avoid the temptation to sign you up to a vague long-term contract. The service provider must demonstrate: a good understanding of the organisation's needs and a proactive contribution in the production of an easy-to-understand protocol, dealing with each logical step of the project. These must be reviewed and agreed by both parties before proceeding to the next stage.

QUALITY

A common misconception is that because a laboratory has been audited by the regulatory bodies then the organisation in turn is fit to be used by other organisations. The quality may well meet the regulatory guidance, but does it meet the standards of the company in question?

You can expect the quality process to be different as the CSO has had different influences on its quality programme when compared with other organisations. There must also be an evaluation as to what is fit-for-purpose and what is reasonable. For example, it is important to ensure that there is an effective corrective action and preventative action program (CAPA) in place which the company can evaluate to assess how it differs from their own – and if so, are the differences manageable? Is that organisation prepared to invest the required time so that the CSO is managed into its own system and evaluate whether the CSO is willing to engage in this additional activity (these type of activities must not be under-estimated?)

Another key area that comes under the quality umbrella is the training programme. The CSO is a service organisation and as such its success will be directly related to its commitment to both customers and staff. The staff must be suitably trained, motivated and appropriately rewarded for their performance. The old idea of keeping analysts hidden behind test tubes and focusing solely on technical skills is no longer acceptable. A sound technical skill base is still an absolute requirement, but analysts in modern CSOs must be able to translate their expertise to the customer in a confident and professional manner. During a working day, the CSO analyst might be the salesperson, technical expert, trouble-shooter and analyst. This is the level of service that organisations should demand from an analyst in a modern CSO.

CULTURAL FIT

The cultural fit of any two organisations is an often overlooked aspect of being a successful outsourcer. This can be one of the most difficult aspects to evaluate, and certainly can be difficult to do remotely. Justification to travel to a CSO is needed, but if they will be undertaking a key

aspect of the supply chain, it is worth considering. The vast majority of CSOs welcome customers and potential customers to their facilities.

By taking this step for key projects, organisations can decide whether the staff and facilities are what is expected. It will also give them an insight into the usual communication styles and provide an opportunity to highlight what significance the work has to the organisation.

A common communication area tested is out of specification/ atypical results. Go into the evaluation process with the primary objective to understand:

- How these situations are handled for the material or product
- What experience does the company have of interpreting the data
- How empowered are the operational staff to undertake investigations
- What kind of involvement is needed
- Who is responsible for taking technical decisions
- How will the CAPA, designed to prevent re-occurrence, be implemented and measured for effectiveness

If this type of situation is not evaluated prior to commencing work, the risks of doing business clearly increase.

INTERACTIVE IT POLICY

The professional CSO must adopt an IT policy that operates in line with the company's own system or approach. This presents a number of difficulties:

1. Modern CSOs are expected to have a computer network that can link all the hardware and software together. Functionally, the ability to communicate quickly both internally and externally is key. It is important to be able to transfer documents to the CSO without delay and have them disseminated with immediate effect to the appropriate people internally.

2. The latest development in business communication is the secure virtual private network (VPN), which allows customers and staff to log onto areas of the network from remote computers to monitor, for example, sample tracking. If remote access is not required, the company should at least be aware of whether this facility exists and the risks of the CSO allowing access to its server containing sample data.

3. A CSO will have an instrumentation network linked to a central server. Furthermore the instrumentation network should ideally comply with 21 CFR 11 regulations if a product is to be sold in the US, for example. The main issue relates to whether or not the instrumentation network should be connected to the internet. This facility is available through instrument market leaders, allowing secure access to results data through a remote server. There are obvious advantages at a scientific level, where chromatographers from both the contract facility and the customer are interested in speedy transfer of data to resolve chromatographic problems as quickly as possible. The resistance comes from a higher level where a more cautious approach is often taken.

   Due to the number of well-documented 'hacks' into major computer networks, many corporate managers are unwilling to have this risk attached to their company. However much a vendor tries to sell the security features of a system, there is always the possibility that, at some point in the future, someone could find a way around them. This caution by some companies causes a conflict within CSOs who have the choice of connecting their instrumentation system to the internet. This could alienate cautious customers while not doing so will be a barrier to business with more progressive customers.

4. The CSO must have an IT development strategy which they should share with clients in order to ensure it meets future needs.

CONCLUSION

Like any business decision, there are many contributing factors in the path towards choosing your laboratory partner, but we believe these points should help in the selection process. Collectively, they indicate the competence of an organisation and, more importantly, their willingness to be flexible to make every project a success. There will be regular dialogue between the CSO and the client before, during and after the project, so it is extremely important that the client feels comfortable with the company and staff involved, and that the supplier is a real cultural fit to the organisation. By investigating these factors, organisations can go a long way to finding the confidence to commit company resources to the partnership.

About the authors

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