

Regulatory outsourcing gathers yet more steam

As another drug development capability, regulatory affairs, continues to be outsourced with acceleration, **Adam Sherlock** of CSC Life Sciences discusses what to consider when outsourcing this function.

The pharmaceutical industry is in a period of reinvention. Based on the numerous mergers, acquisitions, spin-offs and company makeovers, the pharma or biotech company of 2011 is a very different entity from that of ten years ago.

There is no set formula to the changes taking place: some companies are growing exponentially; others, meanwhile, have moved away from the large pharma model. What all companies have in common, however, is widespread layoffs, more euphemistically referred to as downsizing, and a realisation that the days of managing every function in house are long gone.

Outsourcing is today an industry imperative, with more and more functions that were once considered sacrosanct now managed by external partners. In the area of regulatory affairs, that has meant broad change in how the submission process is managed, and by whom.

Drivers for outsourcing

In today's fast-changing business and regulatory climate, many factors drive the growth in outsourcing. The most obvious and frequently cited is cost containment. Departments are slimming down as companies seek ways to improve profit margins without hurting drug development programmes. This is particularly noticeable at large pharma companies that have gone through several rounds of mergers. After all, one of the advantages of converging two organisations is the opportunity to leverage synergies from the combined entities. Equally, though smaller companies have confronted belt-tightening, regulatory affairs departments across the industry are noticeably smaller than they once were.

The potential savings with outsourcing are sizeable. Offshore outsourcing, especially to India and China, offers potential cost savings of 30-60%, a report by Business Insights finds. And as companies themselves are finding, by outsourcing such routine functions as putting together and sending out a product submission, in-house staff members are free to focus on increasingly strategic roles, including regulatory planning across the pipeline. Outsourcing partners can be turned to for staff augmentation at unusually busy times, when unexpected issues arise, or when a company is seeking new capabilities.

Another factor propelling the move towards outsourcing is a global push to standardise processes and procedures, with the drive towards electronic submissions handled in a standardised format – the electronic common technical document (eCTD) – being a prime example. Companies seeking process improvements will often turn to an outsourcing partner to help them make adaptations. Finally, the growth in global markets – and in particular, emerging markets – is creating a need for partners with expertise in parts of the world where a company may not

have a significant presence. This is particularly pertinent given the specific submission requirements each country imposes, and the need to have at least some aspects of the submission of the local language.

A fresh approach

There is more to outsourcing than simply issuing requests for proposal (RFP) and selecting the lowest bid. Many companies have discovered that cheap certainly does not mean cheerful when it comes to project results. The Business Insights report notes that 35-55% of sponsors are dissatisfied with projects, an outcome that is avoidable when well-considered selection procedures get put in place.

Successful outsourcing lies in finding partners that are able to understand and adapt to an organisation's needs and goals, that can perform important yet non-core functions more efficiently than would be possible in-house, and that can do so in a timely manner. As any regulatory affairs professional knows, timeliness and thoroughness are both critical elements when dealing with regulators.

Bringing together those capabilities in an outsourced setting creates economies of scale because handling certain parts of the submission cycle – be that medical writing, report publishing, submission publishing – is what they do, day in and day out, for many clients. The benefit to the sponsor company is the expectation of greater levels of productivity from experienced offshore vendor partners.

There is less rigidity today than ten or even five years ago in terms of what companies are willing to outsource. Where companies at one time would not consider outsourcing anything beyond back-office functions, such as basic report publishing, today companies are turning to external partners for more and more complex functions.

Tactical or strategic

For the most part, companies prefer to hold on to the strategy portion of a function and ship what might be termed "tactical work" externally – increasingly to such offshore destinations as China, India and Eastern Europe. However, technology advances, evolving capabilities and improved training at offshore sites mean that what might be considered strategic today will be regarded as tactical tomorrow. For example, while in the past most aspects of the submission lifecycle would have been considered strategic and the purview of a small group of experts, today many people can put together an entire new drug application, thereby making submissions far more tactical.

There is also a growth market in business process outsourcing (BPO). Even though BPO represents a potentially huge

saving and improvement for companies, the risk is that if the business process is not well-defined, it can be difficult to hand over this aspect to an external partner. Those with experience of working in BPO say companies with well-organised regulatory processes get the most value from partnerships.

There is even growth in what might best be termed “transformative processes”, whereby a vendor has the capability to anticipate future trends in the global regulatory landscape and can implement flexible processes. These are likely to take place once an outsourcing relationship has matured. However, such partnerships can be fruitful only when the company’s expectations have been made clear from the outset. While it is difficult to add that intangible component, the key is to select a partner whose organisational structure centres on innovation.

Managing change

Sweeping changes, such as staff cuts with whole processes shifted to an outsourcing partner, can create gaps and bottlenecks. Staff cuts sometimes result in the loss of certain historical knowledge that can be invaluable to such processes as submissions management. Retaining that knowledge and the consistency of processes management mitigate those risks.

However, experts say, problems that arise in the handoff of work to an outsourcing partner can often be attributed to resistance to change. When bigger process issues arise – for example, the inability to complete a submission within the time frame set by regulatory authorities – companies may be forced into disaster recovery plans as they scramble to find a vendor to meet an urgent delivery. Being prepared to change processes and manage projects in a more streamlined way benefits companies in the longer term.

Assessing risk

In terms of offshore outsourcing, there is understandable reluctance to let go of certain functions for fear of intellectual property breaches, legal wrangles and inconsistencies in quality of work. Indeed, for some companies, such tasks as chemistry, manufacturing and control medical writing are not open to discussion when it comes to working with partners in emerging markets such as China and India. Others say governments have been at pains to give intellectual property high priority and are acting accordingly to create a safe environment for global pharma companies.

All of those risks need to be determined by companies in their assessments of offshore vendors. While cost savings will likely be a top priority in selecting partners, companies need to consider the entire package in their selection criteria. Nowhere is this more pertinent than in regulatory affairs, where a company’s entire product submission may be in the hands of an external partner. Once they have selected the right partners, companies must ensure processes and the business model are followed and contracts are in place to mitigate risk. Given the loss of revenue when copyright is infringed, it is crucial to work with partners that demonstrate strong intellectual property security.

Companies should ensure their partners thoroughly vet and train employees and that the partners have the relevant security management certifications as well as extensive security screening, including cameras that can record and store information. It should not be possible for employees to export data, copy files or remove anything from the premises.

Partnering for the long term

When a department such as regulatory affairs or regulatory operations is selecting service providers it is recommended to limit the number of partners with whom they work, otherwise inconsistencies can arise and cost savings could be negated.

Some industry leaders say there are efforts by functional areas to build trust and understanding with a programme-wide outsourcing partner. For example, the development division at one major pharma company implemented a governance structure to manage and streamline its partnerships. A priority was to distil the number of partnerships from 25 to two, with an exception process in place. Franchises cannot, therefore, simply go out and select partners; they must undergo the governance process to select partners.

There are complexities involved in such streamlining exercises and these are magnified in merger situations when the new entity comes with its own established set of partners. Experts recommend that before a company engages an outsourcing partner, it request and check references during the request-for-proposal process. Not only would the information be helpful in forming a decision, it also would serve to build the relationship going forward.

The emphasis ultimately needs to be on the long-term success of both partners, and that success can be achieved only when the relationship is strong and built on trust. Much of this comes down to the client and vendor having shared values and similar approaches to business.

The outsourcing partner should become an important collaborator in the process, but companies need to retain their own knowledge and capabilities. One recommendation is to have an internal team leader manage the outsourcing strategy. This ensures business continuity as well as knowledge about the process, which is essential if the company needs to make any changes, such as submitting a new formulation to an existing product, submitting to new markets, or changing its approach to submission management. It means the majority of a function can be outsourced, but that there is expertise in house in the event of a sudden need or problems with a partner. It is vital to have in place both good governance and clear delineation on specifics such as scope, costs and timeline.

On the fast track

As the changes taking place across the industry gather steam, companies will increasingly be turning to external partners to help bring their products to market. To what extent companies choose to outsource transformative processes remains to be seen. The trend is towards partnering more as the pressure to cut costs, meet shareholder demands, bring products to market more rapidly and improve the state of product pipelines intensifies. Companies that are best able to reduce their regulatory lifecycles will be best placed to succeed in today’s tough regulatory and competitive climate. ■

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