

Challenges and Opportunities of working with the Pharma industry - A BPO perspective

Dr. K.V. Palanichamy, Tata Consultancy Services Ltd, Mumbai, India
Samidha Sawant*, Tata Consultancy Services Ltd, Mumbai, India
Anagha Bhatkhande Tata Consultancy Services Ltd, Mumbai, India
Balu Ramakrishnan, Roche Products Limited, Welwyn, UK

ABSTRACT

Increasingly, BPO service providers are entering into the Pharmaceutical/Biotech service providers space increasing the amount of choice available to them in terms of the spectrum of services that they are looking for to be done externally. There are many benefits that a BPO organization is uniquely placed to provide. In addition to their Information technology expertise, service delivery and quality focus, BPOs leverage their unique strength in process optimization, thus providing their clients an avenue to them to take an in-depth look at the processes that they follow and optimize them for performance. Working in a global environment while not new to big Pharma companies, working with global external partners (with the exception of CROs) is relatively speaking. However, in the last few years, most of the big names in the Pharma business have taken an active approach to outsourcing and offshoring. In this presentation we discuss our experience as a BPO working with a top 10 Pharma company. We discuss specifically the challenges we faced as we started this journey, the opportunities it has presented us and some of the unique characteristics of the Pharma sector as compared to the other sectors like F&A and IT which have been well established as BPO clients.

1. INTRODUCTION

The use of Information Technology (IT) in the Pharma industry extends right from lead identification to NDA submission and beyond. This has enabled the Pharmaceutical companies to reduce their Time-to-Market substantially. Large volume of data, complexity of study designs and the need to minimize processing time justify the extensive inroads IT has made in the Life Science arena.

The complexity of conducting a clinical trial, its study designs and analysis have increased many fold in the last 25 to 30 years and so it is not even conceivable that Clinical Data Management (CDM) and Statistical Analysis and Reporting without extensive IT support tools and platforms. Such need and use of IT systems and platforms have led to the genesis of highly efficient software packages like Oracle® Clinical, Clintrial™, for paper trials and InForm™, MedidataRave® for EDC trials in CDM and SPSS®, SAS® for Statistical Analysis and Reporting. Some of the highly valuable areas of IT application today are Computer Aided Drug Designs, Quantitative Structure Activity Relationship, Stereo Chemistry and Insilco Simulation model to name a few.

The globalization of Pharma market and growing pipeline of new molecules has dramatically increased the need for professionals having skills to leverage these tools. Shortage of skills, skilled labour and processing capability has led many Pharma companies to start outsourcing. The other critical need that outsourcing brought is, to allow the Pharma companies to now focus their resource and energy in their core area i.e. research and marketing of molecules.

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Until recently, activities like Billing, Financial Accounting, Call Centre Management., etc., were the traditional tasks being outsourced to BPOs. After realizing success in such ventures, IT companies started exploring other opportunities within the auspices of BPO organisations. As most of the major BPOs are offshoots of IT companies, they bring in to their offering spectrum an added advantage of mature Service Delivery Models, Quality Systems, Infrastructure and Data security and Service Level Agreement (SLA) based Delivery which have for years been standard within the IT space.

Today, quite a few BPO organizations have stepped in the ever growing Clinical Research outsourcing space and are providing services in areas like Clinical Data Management, Pharmacovigilance and Statistical Analysis and Reporting.

As is common to any new approach, there are few challenges as well. In this paper, our attempt is to discuss some of the challenges and opportunities that we as a BPO had to overcome and can offer the pharma companies .

2. BPO INDUSTRY

To put a context around our business so far and our foray into the area of life sciences and pharmaceuticals, it is necessary to provide a bit of a background about the BPO industry and its growth over the last 8 years. This is also discussed in an Indian context as the major growth of BPOs including the BPO arms of the traditional multi-nationals like IBM and Accenture has been predominantly in India.

In recent years, BPO industry started to look beyond the traditional financial services, telecom and manufacturing industries to drive its growth. In the last couple of years, the industry has managed to go beyond Voice and Call Centre services to managing back-end processes for their outsourcing partners. BPO has recently entered into what are now known as Knowledge Process Outsourcing (KPO) areas like Clinical Data Management, Pharmacovigilance, Statistical Analysis and Reporting, Market Analytics, etc.

The Pharma industry in their continuous drive to enhance process efficiency, reduce costs and focus on their core business is outsourcing increasingly in areas like Clinical Data Management, Pharmacovigilance, Statistical Analysis and Reporting, etc.

The worldwide ITES/BPO industry is growing at a rate of 9.4% CAGR while the Indian industry is growing at a breathtaking speed of nearly 70% CAGR. In the year 2007, it clocked revenue of US \$ 13,811 Mil. It is now very evident that India is one among the favored destinations for more and more Pharma companies.

TABLE 2.1 - OFF SHORE BPO REVENUE, INDIAN BPO REVENUE AND THE TOTAL WORLD BPO MARKET POTENTIAL

Revenue \ Year	2002	2003	2004	2005	2006	2007	CAGR
Offshore BPO Revenue	1,322	1,825	3,017	6,439	12,563	24,230	78.91
Indian BPO Revenue	912	1,205	1,961	3,928	7,412	13,811	69.35
Total BPO Market	110,167	121,687	131,171	143,090	157,033	173,070	9.45
Source: Gartner Dataquest		Figures in \$ million		CAGR in % 2002-07			

3. CHALLENGES FACED BY THE PHARMA INDUSTRY

As with any other industry, the Pharmaceutical companies too face a multitude of challenges. While not all of these challenges are factors for each and every company certainly each organization face a few of these. These challenges include:

- an acute shortage of domain expert skills
- challenges in recruiting, training
- retaining and managing knowledgeable associates in a context of contractors vs permanent staff..
- pressure from external market factors and internal pressure to reduce costs and enhance shareholder value
- focus resources on core activities like R&D and marketing.
- reduce infrastructure expenses not directly related to core functions
- reduce IT expenditure
- reduce overheads to free up resources to invest in new research
- accelerate development and time to market cycle times

The list above is not expected to be a comprehensive list of challenges faced by Pharma companies today but a snapshot into some of the major issues and pressures faced by most industries. Outsourcing is a method by which companies try and overcome or at the very least mitigate some of the detrimental effects of these challenges. The BPO industry has specific expertise to address a lot of these issues as they were some of the very first issues that they had to overcome as they came into their own.

Take for example, process orientation of BPO companies. This merits a special mention as their genesis depended on developing the ability to break down any activity into discrete tasks and there on each task into several constituent processes and sub-processes. Each process is backed up by Key Operating Procedure (KOP) manuals. Key Performance Indicators (KPIs) are set for each process which defines the quality of the delivery and metrics defined for each. Flow charts and process maps are designed to further elaborate and strengthen the understanding of the task on hand. A feedback mechanism is also laid down through sharing of metrics and regular updates. This is the very core of how BPOs operate.

4. CHALLENGES FACED BY BPO WHILE WORKING WITH PHARMA COMPANIES

Pharma companies are unique in more ways than one. Their operating model itself is one that is specific to the industry. While some of the reasons for this could be the nature of the environment that they operate in some of this can be attributed to historic factors. The factors that make the process unique to in Pharma companies include highly specific domain knowledge. The challenge that this poses when talking about traditional business process outsourcing is that this now assumes the next level of knowledge process outsourcing. Some of the key challenges that we faced are elaborated further below.

In addition to the complexity involved in engaging in knowledge transfer activities, one needs to understand how to specifically tailor SLAs and collate meaningful metrics based on the steps being outsourced. During formative years of the relationship, winning the confidence of each other for smooth functioning of the processes was also a major challenge. This would hold true for all potential companies thinking of embarking on this journey.

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Change management within the client organisation is a major challenge and the Pharma industry is no different from other industries in that their expertise in such a key area is limited. Involving the BPO partner early in this key area would help mitigate a lot of pain for both partners.

Being highly knowledge intensive people with specialized skills are needed to perform the activities like Clinical Data management, Pharmacovigilance and Statistical Analysis Clinical programming, regulatory submissions etc. Recruitment and retention are challenging areas in this domain particularly because this is a nascent activity in India and so specific Pharma experience in the manpower market is currently limited. The availability of talent in of itself does not pose problems for countries like India however, it is scattered across other industries and vast geographical areas. The field is so dynamic that one has to be open to technological change happening in the Pharma industry which again has an impact on the sourcing strategy. Maintaining a strong domain expert team needs continuous flow of business. This in turn is dependent on how this Pharma-BPO tie up is successful.

During initial phases of the engagement, an area of major concern was meeting the expectation of Pharma industry on domain expertise. To address this training covering industry specific knowledge, specific domain knowledge, client processes and also technical skills training all had to be developed.

Attrition is another major challenge in the BPO industry worldwide. This is further exacerbated due to country specific factors in India. The BPOs are working on the observed traits and reasons involved and are taking measures in their recruitment and HR strategies. Employee's interest not only in terms monetary considerations but also their aspirations, drive for creativity, job satisfaction, workplace atmosphere and brand equity all needs to be managed and is a constant challenge.

5. WORKING MODELS

Different working models are available to any organization that embarks on the outsourcing journey. These include a classic vendor client model where work is contracted out with clear deliverables and service obtained which is detailed under specific contract terms, a partnership model where the client makes considerable investment in recruiting, training and developing the relationship and has a mutual stake in the success of the engagement and a hybrid model where it is part partnership with mutual stakes and part a standard contract.

The model that we discuss here is a partnership one and so some of the specifics discussed here may be unique to this sort of an engagement.

To leverage the strong process focused approach of BPOs, the outsourcing partnership is based on processes rather than specific projects or studies/protocols. While outsourcing, the Pharma company gets involved in activities like recruiting, transitioning work/processes, transferring knowledge through trainings, workshops, educate the BPOs in understanding Pharma company's processes, training the associates of the BPOs etc. Thus it is pure collaborative effort of both the parties.

In the following paragraphs we have detailed the steps followed to ensure a successful Partnership Model.

5.1 REQUIREMENT OF DUE DILIGENCE

Once a short list of potential partners has been identified, one needs to understand the potential partners with good rigor. In a Partnership model, one needs to ensure the right fit with the organisation. A host of other factors such as financial, legal, HR, contracts etc need to be studied and so a thorough due diligence process needs to take place from both sides. It is vital that a cross functional team be put in place to ensure that every aspect of the planned process to be outsourced is covered at length and in detail. This is a fairly lengthy process and the importance of spending the time and effort on this activity to ensure future of the long term relationship cannot be stressed enough.

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5.2 VENDOR SELECTION

At the point of selection of a service provider, more emphasis is placed on the levels of infrastructure, training facilities, scalability, quality standards, service delivery, process capability, and the comparative rates of employee turnover. A key critical aspect of selection process is the ensuring alignment of the culture and values of both the partners. This is key as far as process transition is concerned. These are also key areas that affect not only the choice of service provider, but the shape of ongoing governance. The quality of the due diligence visits and the composition and capability of the due diligence teams to cover both operational and strategic aspects of the relationship will ensure a quality decision.

5.3 CONTRACT

A contract is a legally binding document which defines the scope of the project, fee structure, milestones measurement metrics, escalation process, the jurisdiction and allied terms and conditions. The true test of the contract lies in both parties ensuring that all aspects of that are followed not only in words but also in spirit.

5.4 TRANSITION

This step is where the company and the partner BPO mutually discuss and lay down definite processes for the company's outsourced activities be it Clinical Data Management, Pharmacovigilance or Statistical Analysis and Reporting. Each of the outsourced processes is discussed and a clear-cut process transfer is agreed upon by the parties. The transition team normally travels onsite for high level process understanding and activity analysis. Key metrics of interest in the process are identified and detailed process maps are drawn out and both parties agree on the overall process and metrics as laid down. Process risks are identified and process reporting requirements (Team Charter, Communication Plan, etc) are put in place. A Failure Mode Effect Analysis (FMEA) is carried out to ascertain potential risks and mitigation plans for these risks. During this process, the skill sets of both the companies compliment each other. Various processes like communication flow, training, work flow etc are also discussed in detail and the steps involved in all these processes are documented for further reference.

5.5 RECRUITMENT

The onus of providing a proper estimate of required resources and the skill set that they need to possess rest with the pharma company. Recruiting talented resources to perform the highly skilled job would be the domain of the BPO partner. While the BPO partner's HR is involved in the entire process of searching suitable candidates, screening the CV's, scheduling and conducting interviews, the pharma company may choose to provide insights into candidate CVs and recruitment strategies. They may also have input into final selection ratios and sometimes retain a say over who is recruited as first line and middle managers who are chosen to lead the engagement.

5.6 TRAINING

The initial training normally would be the partner company's responsibility and would for the most part relate specifically to the systems and processes they use. They may choose one of the many different models available. In highly knowledge intensive operations, the most common approach would be to depute trainers or Subject Matter Experts (SMEs) to transfer the domain knowledge. Depending on the process area, the trainers provide well developed training material and impart the process knowledge to the associates in the BPO partner company. Depending on the needs, a training strategy has to be devised, a training plan developed and the training curriculum designed in such a way that at the end of the training, the BPO partner's associates become well versed with the company's outsourced process. A well planned training plan would include sufficient hands-on time, practical examples, quizzes and role plays to ensure optimal learning. In addition, often an assessment and qualification process may also be put in place to ensure quality of the BPO partner

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employees and their understanding of the processes. A train the trainer model may also be implemented so that the BPO partner eventually takes on the responsibility of providing training to future candidates. This kind of client involvement in the training process is a unique characteristic of Partnership Model as it also helps in cultural exchange between the two parties.

In addition, several other aspects of operations may be covered by the BPO's own Learning and Development department. These could include understanding the organization, core values, organizational behavior, mission, vision and policies that are followed by the BPO. Some general technical training could also be provided on the domain front with the support from various other SMEs within the BPO and followed up with specific technical skill training required to perform the job.

5.7 PILOT

After the associates are certified on the training and the processes, practical work to further enhance the skills of the associates are normally provided by giving one or more pilot project work. This also provides another avenue to assess the quality of work being produced in a live situation as opposed to an artificial training or assessment situation. Another important outcome of this process could be that development needs of the team and or individual team members could be prepared based on the assessment of their work on pilot projects.

5.8 PROCESS

The BPO contributes to defining the processes, setting quality systems and standards, collection of metrics during execution of the process, measuring the health of the process and once a certain level of maturity has been attained to potential process improvements. The insights achieved from this process can be used to do potentially extensive process re-engineering, that may benefit the Pharma Company.

5.9 GOVERNANCE

A key component of any successful partnership is the governance models that need to exist to manage the relationship. A structured model would cover right from the operational aspects of the relationship right through to an executive level depending on how deep the partnership is. Both partners need to have parallel models with adequate levels of cross match. This would foster mutual understanding at all levels and also enable early identification of potential issues and facilitate open communication. A good governance model would also provide forums for joint discussion of common issues and facilitate development of mutually acceptable solutions.

6. CONCLUSION

The outsourcing of Pharma work is a trend that is clearly gaining momentum, as pharmaceutical companies reach deeper into their business processes to reduce costs and enhance performance and focus on core activities. As the BPO organizations broaden their horizon in these types of areas and the CROs strive to retain their market share and compete with the BPOs on equal footing, both types of provider organizations will enhance their operations with the right people thus providing an overall gain to Pharma companies.

With strong process optimization and deep involvement of client, BPOs can provide much more than the SLAs. Their contribution in process re-engineering adds value to the client's own business model. An approach with a partnership model adopted by BPOs is a clear win-win situation.

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CONTACT INFORMATION:

Your comments and questions are valued and encouraged. Contact the authors at:

Dr. K V Palanichamy
Ph: - +91 22 67786059
Email:
v.palanichamy@tcs.com

Samidha Sawant
Ph: - +91 22 67786058
Email:
samidha.sawant@tcs.com

Anagha Bhatkhande
Ph: - +91 22 67786056
Email:
anagha.bhatkhande@tcs.com

TATA CONSULTANCY SERVICES LIMITED

4th floor, Empire Plaza,
L.B.S.Marg, Vikhroli (W),
Mumbai - 400083, Maharashtra
India