



INSIGHTS

R&D Outsourcing in Big Pharma The latest trend: Is it for you?

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Market Overview

By 2010, we predict that 50% of Big Pharma R&D will be outsourced to more capable firms in order to maintain a strong and vital pipeline of new blockbuster drugs. This will result in greater profitability and increased shareholder value for the early adopters of Big Pharma.

—Neil J. Nelson, for Clarkston Consulting's Advantage Advocate

The pharmaceutical industry continues to dominate the global landscape as one of the most successful and profitable markets. It is estimated that the “combined worth of the world’s top five drug companies is twice the combined GDP of all sub-Saharan Africa.”¹ Traditionally, pharmaceutical company successes have been dependent on innovation and research and development (R&D) efforts, which are responsible for bringing new blockbuster drugs to market. Today, pharmaceutical companies are met with many challenges as they attempt to continue their success and appease strong masses of shareholders. Some of the most daunting challenges currently facing the pharmaceutical R&D executive include:

- Shorter product lifecycles
- Slow FDA approval times for new drugs and changing requirements

- Increased competition
- Lack of ingenious and innovative R&D

Expediently capitalizing on R&D expertise, or intellectual property as coined by the Advantage Advocate committee,² is an important success factor in today’s competitive business climate. Some pharmaceutical companies have taken the course of mergers and acquisitions to address filling their pipelines, while others have started taking a daring step in outsourcing R&D in order to ensure an attractive and robust pipeline to support their future. Over the past decade, outsourcing solutions have commonly been applied to the pharmaceutical industry in the clinical development and testing phases.

Now, a more pressing issue, which seems to uncover more benefits than disadvantages, is extending outsourcing to pre-clinical development tasks, i.e., drug discovery. Smaller, creative, more nimble operations are unencumbered by big company inefficiencies that often wreak havoc on big pharma’s R&D functions. Additionally, properly focused quality processes in early stages of R&D can optimize and improve the efficiency of drug development, resulting in reduced time to market the drug and better control of new product launches.

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This paper will examine the shift in attitude of big pharmaceuticals' increasing willingness to use outsourcing suppliers in the early stages of drug discovery, as well as what we predict to be tremendous long-term results of this evolution.

Outsourcing—Do You Know the Facts?

Consider these statistics, which illustrate the explosion of R&D outsourcing onto the pharmaceutical scene:

- In 1998, U.S. pharmaceutical companies outsourced 15% of their manufacturing projects, 21.5% of their clinical evaluations, and 14% of their R&D endeavors.³
- In 2003, CROs accounted for about 20% of the pharmaceutical and biotechnology R&D budget.⁴

Outsourcing relationships between companies are often complex and not easily defined, and differ based on the services outsourced, and management approach to outsourcing activities, as well as how much control they exert. In some outsourcing relationships, the buyer may not instruct the supplier on how to deliver results by performing a set of tasks, but may only be interested in achieving the desired results. However, in other cases, the buyer may seek more involvement and control in defining how the results should be delivered.

According to Advantage Advocate, the evolution of outsourcing has moved through three phases, namely:

- Outsourcing of support functions.
- Process outsourcing of core functions.
- Value-added partnering.⁵

To most people, outsourcing is associated with non-core, mundane activities that are generally the non-strategic support functions in an organization, such as IT infrastructure support or telephone maintenance. More recently, outsourcing core business processes has become increasingly popular, and outsourcing solutions have become geared towards stripping the cost of large-scale, manually intensive business processes through BPO (Business Process Outsourcing). Some of these core functions include managing back-office operations such as accounts receivable, payroll, and MRO purchasing.

Partnering with outsourcing services providers facilitates the organization's processes to improve organizational efficiency and lower operating costs. More

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recently, and in consideration today, is value-added partnering, which benefits companies in areas that are more connected to the company's ability to grow and increase shareholder value. Value-added outsourcing partnerships are often referred to as strategic alliances or joint venture relationships. Examples of value-added outsourcing include activities involving manufacturing, marketing, and R&D.

Strategic alliance, the fastest growing type of service partnership, aims to deliver client value with creative solutions and project management skills, and structure meaningful contracts that accommodate change. These alliances also allow the outsourcing agents to pursue full-service and/or global outsourcing deals.⁶ On the other hand, joint venture is a type of relationship that "offers a new business model for outsourcers to work more strategically and creatively with their clients and potentially develops revenue-producing business opportunities."⁷

Focus On R&D

Pharmaceutical companies have their greatest assets in R&D, the "crown jewels" for any growing pharmaceutical company. Double-digit growth and escalating market caps are not possible without the consistent advent of new blockbuster drugs. Many executives are sure to balk at the notion of letting the livelihood of their firms be the responsibility of another, but over time, this will change. In fact, pharmaceutical companies can extrapolate on the lessons learned from the biotech market and from experiences in partnering with academic institutions to research new drugs. According to the Centre for Research in Innovation and Competition (University of Manchester), "Firms, even Large Multi-National Corporations, can no longer expect to be totally dependent on their in-house research and technology resources to maintain innovative performance."⁸

Another drive for cooperation and outsourcing in R&D is expected from FDA and other regulatory authorities. FDA is determined to improve the review and approval processes to help highly effective drugs and new therapeutic principles become available faster. However, safety concerns require more and often additional tests, and cause delays for the time to market of all pharmaceuticals. A development for a specific patient population will definitively shorten development time and cost, and may also help improve the safety of a novel drug. Mandatory are selective diagnostic tests that provide enough information about a target patient group to provide effective drugs with a tolerable side effect profile. Big Pharma is well advised to include in their R&D program cooperative steps with diagnostic research facilities to incorporate the relevant assay development for selective test into their development process. Roche and Johnson & Johnson have excellent in-house diagnostic capabilities; other Big Pharma companies will have to develop such capacities by acquisition, out-sourcing, or other forms of cooperation.

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Current Trends in the Pharmaceutical Industry

Less than 10% of products researched become viable blockbuster drugs.

Pharmaceutical companies have increasingly turned their focus to acquiring external pipelines and products in order to deal with the intense pressure of drug discovery. Generic drugs are entering the marketplace at an increased rate, doubling their share of the prescription market from 18.6% at the end of 1984, to 47.1% in 1999. Since the passing of the Competition and Patent Term Restoration Act of 1984, pharmaceutical companies have less than 12 years to recoup investments on R&D for drugs they seek to produce and sell to the public. Pharmaceutical companies are faced with shorter lifecycles from the conception of a drug to the marketing and full-scale production of the drug. In addition, the core motivation driving pharmaceutical companies is the capability to engage in research that results in a blockbuster drug, and less than 10% of products researched become viable blockbuster drugs.

To respond to shorter product lifecycles, cost-containment pressures, and limited research opportunities, pharmaceutical companies have formed industry consolidations in order to maintain a robust pipeline. Industry consolidations through acquisitions have been next to common within the big pharmaceutical companies. Even major players such as Pfizer have turned to mergers and acquisitions in order to gain a competitive edge, announcing that it “has agreed to pay \$1.3 billion in cash for Esperion Therapeutics in the hopes to gain profits from Esperion’s potential blockbuster drug—ETC-216, which is the first medicine to actually reduce the amount of cholesterol plaque in arteries.”⁹

Food for Thought

Before engaging in the outsourcing of R&D activities, pharmaceutical executives must ask themselves some key questions, carefully weighing the pros and cons as they seek out innovative approaches. Below are just a few questions to consider:

Is it more effective to outsource certain R&D activities to an innovative organization than to acquire that organization?

Yes. If the innovative organization is acquired, then its inventiveness will over-time become stifled by the controls that are inherent to larger organizations. The regulatory controls are the same for all firms involved in the manufacture of pharmaceutical products. Smaller, innovative organizations save a great deal of time in areas such as purchasing, HR, and communication because decisions are usually made quickly, and action is taken that results in a shortened cycle time.

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Are larger pharmaceutical companies more capable of cGMP compliance than a smaller, innovative organization?

No. Compliance with cGMPs is actually easier to achieve in smaller, innovative organizations. Once alignment has been achieved regarding compliance deliverables, the innovative organization will quickly organize to achieve these deliverables.

Is it true that smaller, innovative firms can do things faster because they are willing to take risks that large, established pharmaceutical firms will not take?

Yes, but these should not be regulatory exposure risks. There are risks that can be taken that do not compromise cGMP compliance. Employees at smaller, innovative firms are often encouraged and empowered to both propose and take risks that close the gap between scientific soundness and compliance with cGMPs. This culture and modus operandi are effective in lessening the time required to move a compound through the R&D process.

Does acquisition (compared to outsourcing) provide more control of proprietary information?

No. Firms that provide outsourcing services are highly motivated to protect their customers' information. It is in their interest to do so in order to protect their reputation and secure future business.

Is in-sourcing a team of innovative people as effective as outsourcing to a similarly innovative organization?

No. Although in-sourcing can work in a highly disciplined and well championed environment, in reality the in-sourced group will tend to lose its innovative edge as influenced by even limited sponsor management and QA oversight.

The Growing Trend of Outsourcing R&D

Before the '90s, the pre-clinical stages of R&D, particularly drug discovery, were not outsourced, often because of the proprietary and secrecy issues surrounding patented information. Now, even big pharmaceutical companies recognize the need to outsource drug discovery. This shift in attitude is attributed to the fact that most drugs that are marketed today were not discovered in-house. There is more intellectual property outside of the organization, especially with the impact of genomics and proteomics in therapeutics. In most cases, outside discovery work proves to be cheaper and faster. Contract Pharma predicts that for 2004, some companies that will recognize the need to "keep adding to its

Most drugs that are marketed today were not discovered in-house.

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technological capabilities not to just increase capacity are: Baxter Pharmaceutical Solutions, Hollister-Stier, Abbott One 2 One, Patheon, DSM Pharmaceuticals, and the Ben Venue division of Boehringer-Ingelheim.”¹⁰

Pharma companies have traditionally been willing to forge alliances with outside organizations to generate new ideas and be on the brink of new breakthrough technologies, which historically had roots in academia or biotech firms. This form of outsourcing—pseudo strategic alliances—includes:

- Pharmaceutical companies partnering with biotech firms
- University research centers
- Contract research organizations
- Other third parties

Pfizer has more than 250 partners in academia and industry, which has “strengthened the company’s position on the cutting edge of science and biotechnology.”¹¹ These alliances have allowed pharma companies to use other organizations’ research expertise, bring products to market faster, and mass produce drugs after FDA approval. However, a more pressing need is to move toward the formal outsourcing of R&D activities to established firms which specialize in the business of R&D outsourcing, particularly in the area of drug discovery. Recently, industry giant Johnson & Johnson Pharmaceutical Research Development partnered with 3-Dimensional Pharmaceuticals (3DP), which will apply its technologies to discover and optimize small drug leads directed to genomics targets identified by Johnson & Johnson. 3DP is also eligible to receive milestone payments and royalties on any sales of resulting products.¹² Thus, R&D outsourcing is becoming not just a trend, but a way of life—and survival—for even the largest pharmaceutical companies.

R&D Innovation and Virtual R&D

Outsourcing virtual R&D can bring about new ideas and innovation that are not present in-house, and give the company a competitive edge, particularly in decreasing time to market. The virtual R&D outsourcing services provider should have the best expertise for every function, as well as multiple service offerings and a high mastery of innovation. The outsourcing of data management in pharmaceutical companies is becoming increasingly common as a method of virtual R&D. According to Chemical and Engineering News, practices of outsourcing data management are becoming popular amongst large pharmaceutical companies.¹³

Some current examples of technological advances in virtual R&D outsourcing include:

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Clarkston's EDA solution for GlaxoSmithKline¹⁴

GlaxoSmithKline contracted Clarkston Consulting Canada to develop and operate an Electronic Data Archive (EDA), one of the first data archiving systems of its kind in the pharmaceutical industry. EDA manages highly confidential and business-critical scientific research and development data, and provides an archive for digital data of staff working in regulated environments of GxP. The benefits of EDA will be to provide patent protection and legal protection, especially in regulatory areas so that FDA pertinent data can be stored over extended periods of time. EDA has also enabled knowledge sharing.

CDM (Clinical Data Management) solution for Wyeth

According to Forrester, Wyeth signed a 10-year outsourcing agreement with a consulting company to take over the CDM process at Wyeth. Robert Ruffolo, president of R&D at Wyeth stated, "by handing transactional data management function to a firm...a drug company like Wyeth can decrease cycle times and drive costs down by millions of dollars every year."¹⁵

R&D Outsourcing—Pros and Cons**Reorganization Benefits**

In the pharmaceutical industry, some proponents of outsourcing R&D activities cite the need to have a tighter focus on core competencies. With outsourcing, organizational benefits exist whereby pharmaceutical companies are able to redistribute internal resources to best support core business functions post an R&D Outsourcing arrangement.

Greater R&D Business Benefits

According to the Advantage Advocate forum, outsourcing will bring many R&D benefits by:

- Reducing development time
- Decreasing the cost of development
- Generating greater revenue

Outsourcing requires a long-term commitment, but will generate tremendous benefits if done correctly. In addition, multiple products can be sought with the help of outsourcing, thus yielding a larger pipeline and an expanded product portfolio.¹⁶

Reduced R&D Complexity

Outsourcing also helps reduce R&D complexity,¹⁷ which is sometimes faced by large pharmaceutical companies. In order to develop competent intellectual property, outsourcing provides:

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- Access to technological innovations
- Rapid access to additional R&D capacity
- Access to therapeutic expertise
- Alignment with diagnostic tests for safer and more effective therapies

Financial Benefits

According to the Advantage Advocate Forum, outsourcing enables the supplier and buyer to:

- Share costs
- Share benefits
- Decrease development risks
- Improve profitability
- Overcome liquidity bottlenecks

The buyers' up-front capital requirements are reduced and operating costs are controlled. With these financial benefits, outsourcing works best in increasing profitability.¹⁸

Concerns of Outsourcing

Proprietary Concerns

When outsourcing any key business activity, it is important to ensure that core intellectual property is not at risk of being given away. A trust/partner relationship must be fostered with the outsourcing supplier.¹⁹ The pharmaceutical company should decide what key strategies and confidential information should be shared with the supplier, and have it captured in a carefully structured legal agreement.²⁰

Management Concerns

Outsourcing activities require efficient management skills to facilitate the progress of bringing the drug into the pharmaceutical company's downstream pipeline processes. The management process has to be agreed to by both supplier and buyer. There may be a concern on the buyers' part of ultimate loss of project control if the outsourcing relationship is not managed correctly. Additionally, management needs to assess the temperament and impact on internal employees of the outsourcing activities, and ensure that low morale does not result. Managers with clear responsibility and knowledgeable and empowered staff are needed to oversee management of outsourcing activities.²¹ In addition, management must be flexible so that the supplier can deliver creative solutions.

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Establishing Good Standards

According to the Advantage Advocate Forum, a well-defined process needs to be in place as technology and design requirements are transferred and communicated; each activity needs to be carefully assessed and recorded. In order to evaluate delivery of products and services, Quality Standards and associated performance metrics need to be determined early on in the outsourcing agreement.

Best Practices for Outsourcing R&D

Contract

The key issue in a successful outsourcing relationship is for the supplier to understand the buyer's goals and objectives. In the outsourcing agreement, a strategic vision and plan²² must be scoped out that defines a common set of objectives. A properly structured contract containing expectations of both the buyer and supplier and incentives to make the relationship work needs to be tailored.

Trust

There needs to be open communication during the life of the outsourcing agreement. Outsourcing suppliers require open and honest communication, and trust is naturally established on shared information. Quality time needs to be spent between the supplier and buyer, and integrity and clear expectations should be developed.²³

Professional

Both the supplier and buyer need to enter into the relationship with openness, and accept that cultures of both supplier and buyer could be different. A paramount relationship requires:

- Team-building endeavors and new work processes as needed
- Documentation of all agreements so that and neither party is misled
- Senior executive support
- Outside advice to foster a successful relationship
- Development of people's collaboration skills
- Establishment of clear governance and measurement processes to assess progress

In addition, do not ignore personnel issues, and address them with good management skills.

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Management

In the outsourcing relationship, a great management process can either make or break the deal. Effective results of cutting operating costs in the pharmaceutical company could fail if a good management system is not in place to provide guidance and accountability. Key predictors for great management are finding a great leader, who need not be from either the supplier or buyer companies. Also seek an executive sponsor who will have ownership of the project and will:

- Provide clear direction for projects
- Remove any obstacles
- Resolve problems quickly
- Give advice and guidance in vendor selection for outsourcing efforts
- Provide reinforcement and encouragement²⁴

The Program Management Office (PMO) is an effective management solution that has been shown to deliver projects on time and budget, cut costs, and improve efficiency. The PMO's main responsibility is to instill a level of structured leadership and methodology across all projects and make the best use of resources. The objective of a PMO is to promote consistent, repeatable practices that result in successful projects and use business resources efficiently. A successful PMO can provide guidance in assessing outsourcing options resulting in plans to understand and leverage alternatives for achieving greater results and improved services. In addition, the PMO solution offers a risk-mitigating, on-going governance structure for an R&D outsourcing relationship. It has an effective management structure with the right controls in place.

Conclusion

By 2010, we predict that 50% of Big Pharma R&D will be outsourced to more capable firms in order to maintain a strong and vital pipeline of new blockbuster drugs. This will result in greater profitability and increased shareholder value for the early adopters of outsourcing concepts.

The pharmaceutical industry is currently in a very challenging period. The days of blockbuster drugs filling product portfolios and year over year double-digit top line growth are becoming much harder to realize. Firms that are able to adapt to this new paradigm will emerge as the new leaders in this industry. Some of the household names from the past may find themselves scrambling to secure their future and maintain their level of confidence with investors and shareholders.

It will be those companies that are able to step outside of their own sand box and reach out to small and more focused, research-oriented specialty firms that com-

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plement their traditional processes. One challenge those large houses will face is harnessing the intellectual capital and sheer energy into a disciplined approach which can lead to success. Companies that can infuse an excellent and balanced Project Management capability with an emphasis on control of schedule slippage and cost overruns without compromising outcome deliverables will rise to the top of the industry. Maintaining a consistent methodology related to GxP compliance around deliverables that will be the subject of regulatory inspections prior to product distribution will help fend off any unwarranted delays in product development cycles.

In short, it will be firms that have invested in the development of their internal and external business practices, and can then successfully port that discipline to their development partners, which will lead the new pharmaceutical model for the 21st century.

About the Author

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Notes

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About Clarkston Consulting

Clarkston Consulting is a nationally recognized management and technology consulting firm that provide validation, compliance and implementation services to address issues that its clients face in FDA-regulated environments. Nearly half of the top 50 pharmaceutical companies in the world have worked with Clarkston's consultants, who deliver award winning expertise and exceptional customer satisfaction. Clarkston Consulting's approach focuses on the key business drivers aimed to improve productivity of product development pipelines; communications between sales, marketing, and customers; and business processes centered on new product launches. To learn more about Clarkston Consulting, visit www.clarkstonconsulting.com/whitepapers.



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