CHAPTER – 6

OUTSOURCING IN INDIA

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OUTSOURCING STRATEGY

6.1. Introduction

In the earlier chapters we saw how the pharmaceutical industry has undergone the significant changes in terms of quantity, quality and structure. Of the many changes the pharmaceutical industry is undergoing since years outsourcing appears to be the latest one. Traditionally the pharmaceutical companies used to be one unit ranging from drug discovery, manufacturing, packaging and marketing all in one management. The situation is changing in-house resources because of product lines change due to many products going off patent, low productivity of R and D and higher cost of product approval. (Schweitzer O. Stuart, 2007) Due to these reasons many companies of advanced world are outsourcing one or more of their activities to outside sources. Every year expenditure on outsourcing of contract research and manufacturing services (CRAMS) are rising. Outsourcing activities can be on various fields' right from the drug discovery till manufacturing of products. As mentioned in earlier chapters India is a large beneficiary along other developing countries. (Schweitzer O. Stuart, 2007)

In this chapter where various aspects of outsourcing have been discussed .Section two deals with trends in outsourcing, third section deals with Outsourcing in India. Section four specifies growth opportunities in India and lastly to conclude the benefits, risk and concerns of outsourcing has been discussed.
6.2. Trends in Outsourcing

Companies increasingly seek external collaborations as a strategic move that gives them a competitive advantage and provides them with access to high-level specialization that would be far more expensive to establish and maintain in-house. (Schweitzer O. Stuart, 2007) However, a commonly held concern is that by forming such an alliance, a pharmaceutical company risks losing its own skill sets, thus growing more dependent on the specialist company (Drug Discovery and Development 2000). Notwithstanding such concerns, recent trends confirm the attitudes of pharmaceutical company directors who argue that outsourcing in drug discovery will continue to increase far as developed nations are concerned (Porter, 2000). For many pharmaceutical manufacturers, contracting with an outside specialist to handle a particular process or step of product development can offer benefits because the outsourcing firm, by specializing in a particular aspect of pharmaceutical research and development (R&D) or marketing, can achieve economies of scale that a larger, more diversified company cannot achieve by itself. In many cases, companies simply do not have the necessary technologies, skills, time, or access to raw materials or production infrastructures required to complete the essential development, manufacturing, or marketing steps efficiently (Purchasing Magazine 2000).

Pharmaceutical firms of the developed nations have realized that outsourcing significant amounts of their operations to low-wage countries is becoming an integral component of sustaining profit levels. Few major pharmaceutical companies do not already have pilot programs in place or plans to offshore sizeable components of their operations. According to one estimate in this sector alone. Off shoring is expected to
increase by 16 percent annually, driven by robust increases in the augmentation and relocation of both back-office and core processes. (Schweitzer O. Stuart, 2007)

Pharmaceutical companies - in house, outsourced, or a hybrid - ensures that the benefits low-wage countries offer can be enjoyed by all types of firms in the drug industry. The relationship utilized by a drug company is a function of several factors: amount of employees required; the offshored function's sensitivity to IPR loss; long term goals of the drug company; core competencies and expertise of the drug company; and scope of the functions to be offshored to the same firm or location. Wyeth's recent partnership with Accenture demonstrates that a pharmaceutical company need not set up shop in or hire a firm from India to take advantage of the cost, time, and expertise the country has to offer. (Schweitzer O. Stuart, 2007)

At global level not all companies have relied solely on others to perform their offshored R&D. Pfizer recently doubled the amount of money it invests in its Indian clinical research operations to roughly USD13 million. In 2004, GlaxoSmithKline performed 10 percent of its clinical trials, in low-wage countries." It plans to increase this to 30 percent by the end of 2005. Companies were originally driven to offshore for cost-saving reasons, but are now beginning to capitalize on revenue-enhancing opportunities. This will further pressure those that have not adopted global resourcing to find new sources of distinctiveness, reduce costs domestically, or engage in offshoring." (Schweitzer O. Stuart, 2007)

In developed countries like USA, Canada Offshoring is quickly becoming an essential component of the pharmaceutical industry. Pilot programs are commonplace...
and plans to expand overseas operations are a standard response to increasing cost pressures. Next to the major pharmaceutical companies themselves, India's pharmaceutical sector and its economy in general are the biggest beneficiaries of this trend. The drive to outsource more, both in magnitude and in scope, is inevitable, and India is the place to do it. Firms will still be saying "yes" to the "should we offshore" question in ten years, but "India" is not necessarily the permanent answer to the "where" question.

Outsourcing is so prevalent at global level that the number of specialty firms has grown rapidly. In the biopharmaceuticals area alone, some 80 companies offer contract manufacturing outsource services globally. Approximately 185 global pharmaceutical or biotechnology companies currently outsource some or all of their biopharmaceutical manufacturing, including some of the largest of the pharmaceutical firms, such as Abbott Labs, Eli Lilly and Com., Pfizer, and AstraZeneca (Drug Discovery and Development 2000).

It is difficult to predict how these models and strategies used by pharma companies of the advanced world will change because many of the biotechnology and pharmaceutical companies make outsourcing decisions on a case-by-case basis rather than follow a consistent strategic policy. In addition, the large pharmaceutical companies are just now starting to formulate outsourcing strategies for biopharmaceutical production. Priorities within these firms may differ as well. For example, corporate executives may favor the outsourcing model because it allows a firm to concentrate on its core strengths, whereas manufacturing managers may be resistant because they want closer control over each stage of manufacturing all these
changes will have significant implications on the pharmaceutical sector of India as we are the ones who are in the business of outsourced work. Now let us discuss the more details in subsequent section. (Medical and Healthcare Marketplace Guide, 1999).

6.3. Outsourcing in India

Outsourcing in the pharmaceutical industry is the establishment of relationships with external firms to conduct some of the tasks necessary to bring drug product to market. Those activities can include the discovery of new chemical entities of more convenient method of administering an already discovered product, the conducting of large scale clinical test of new products or marketing of the finished product. (AT Kearney, Sept 2004)

Outsourcing allows a pharmaceutical company to focus on its core competencies while contracting with the external partners whose expertise complements their own. Under this arrangement the ultimate benefit accrues to both the major pharmaceutical company and the partners. As the cost of pharmaceutical development continues to rise, more and more drug company look to the joint ventures as means to capitalize on the complementary strength of the other partner and outsourcing critical process becomes important strategic step. These relationships occur between the large established company, between large firms and smaller companies and even between the potential advantages from outsourcing:-

- Cost saving
- Expertise
- Speed and flexibility
• Process improvement
• Variable instead of fixed cost
• Avoidance of big capital outlays
• Opportunity to focus on core competencies

Cost saving: The opportunity to save payroll costs can be huge, especially in lower wage offshore labor market. Eg India’s highly educated, skilled and English speaking workforce earns fifth to a tenth of what is earned by US worker. For a company in U.S.A. this is a cheaper cost of production without any doubt.

Expertise: If a firm lacks skills, outsourcing can help whether it is small company with limited means or a large firm that must marshal existing resources more effectively.

Speed and flexibility: Outsourcing can get operations up and running more quickly. Outsourcers can provide a shortcut to radical improvements in efficiency cost and speed by dislodging deeply entranced habits and processes. By starting from scratch, outsourcers can implement new and better methods as matter of course.

Variable instead of fixed costs: The ability to avoid huge fixed cost is attractive. Outsourcing allows using our capital more efficiently. New companies have limited financial resources so we have to choose where we spend it. It is better to spend on science and technology rather manufacturing plants. The maker of drugs to fight infection does most high brainpower tasks internally and outsource more transactional activities including manufacturing, payroll and clinical trials data management.
Opportunity to focus on core competencies: Outsourcing non core and transactional tasks can free a firm to concentrate on what it does best. In the increased off shoring makeup occupational employment as companies take advantage of skilled labour in low wage countries. A surge in blockbuster drug sales improved marketing strategies and relaxed regulation will speer job creation.

Historically even in advanced nations, the pharmaceutical industries has been slower to embrace off shoring but over the last few years this trend has begun to reverse with significant movement toward global sourcing. At the forefront of this wave are the large multinational corporations based in the US, West Europe and Japan.

Unlike many industries the pharmaceutical sector is uniquely positioned to remotely execute one of its core competencies R and D which represents 74% of off shored employment and D covers a variety of areas but the activities currently performed in less developing nations like India include clinical statistics data management , medical writing and discovery. The pharmaceutical industry has recognized clinical trials as an area with greatest potential of cost savings and expansion. Eg Quintiles, a well known provider of clinical trials has hired 850 employees in India or 5% of its total employment and plans to expand its data management centre in Bangalore. (AT Kearney, Sept 2004) Employments of numerous positions are currently being globally resourced. Since R and D constitutes the largest offshore operation many life Science researchers, doctors and nurses have been employed in low wage countries including India to conduct clinical trials , drug discovery and other research functions. Analysts, financial experts, accountants and generalists have been hired on a smaller scale to support R and D and human resources. Therefore it is crucial that global
pharmaceutical companies work with competent and flexible local partners to conduct these operations. (AT Kearney, Sept 2004)

A report by Preston and Singh states that the global manufacturing offshoring will increase from USD 14 billion to USD 27 billion by 2007. India’s inherent advantages in both contract manufacturing and research make it an attractive destination for the mass production of drugs and clinical research. (Gupta Amar, 2006) The existing Indian pharmaceutical industry is well known for its ability to quickly reverse engineer patented drugs and the availability of low cost trained chemists.

Indian companies have also built manufacturing facilities, which could quickly be updated to international standards. In fact, in India there are 70 United States Food and Drug Association (USFDA) approved plants and over 200 units certified as following good manufacturing Practices which are highest in number outside US. (Gupta Amar, 2006) Indian companies would also make excellent partners for fewer drugs which are being discovered. Moreover the ones that are developed are costing more to get approved. These increased R and D costs can be seen throughout the drug development stages. Tremendous pressure is being placed on drug discoverer to speed innovation. In addition to a rise in the cost of developing new drugs and a decrease in the frequency of their discovery, the increasing use of generic pharmaceutical is putting pressure on firms to cut costs. The increasing cost of R and D makes low cost alternatives such as offshoring to developing nations like India all the more attractive. (Gupta Amar, 2006)
**Cost differential:** India has many talented chemists from years of reverse engineering drugs developed in US and West Europe. While this wealth of labour doesn’t extend to scientists with managerial experience – integral such as life sciences and analytics. Glaxo Smith Kline is leveraging Indian talent in its alliance with Ranbaxy under which Ranbaxy identifies promising potential drugs and performs preclinical trials, while GBK performs later stage development and retains the right to market the drugs in all countries than India.

**Time to market:** Without patent, pharmaceutical and biotech industries would collapse. Patents provide the monopoly power to producers that enable them to recoup their enormous R and D costs. Without exclusive rights to produce and sell patented goods, generic would dominate the market. Each year of drug’s patent protected life is extremely valuable. This time period is affected by two dynamics: patent length, which has been fixed globally by WTO and no less than 20 years, second: the time from the date of a patent is filed and its debut on the market. Off shoring has the potential to significantly reduce this development time.

Off shoring can alleviate this time crunch by speeding clinical trials. Drugs companies in West Europe, the US and Japan face regulatory requirements for approval. In order to meet these standards extensive clinical trials must be conducted. The population of developed countries is generally less. Conducive to these trials than developing countries. Complementing this superior access to patients for clinical trials, off shoring enables companies to work as multinational pharmaceutical companies hence they filed a total of 126 drugs Master Files with USFDA in 2003, ranking only second to the US and constituting 20% of all drugs entering the US market. Thus India
possesses a talented workforce and efficient manufacturing infrastructure that is suited for off shoring. (Gupta Amar, 2006)

The Indian government now allows 100% of Foreign Direct Investment (FDI) to directly flow to the pharmaceutical industry. (Gupta Amar, 2006) Reduced import tariff and price controls have also made India a more attractive destination for FDI. The movement towards investment climate was motivated by the low level of R and D investment by domestic pharmaceutical companies. Historically also Indian firms devote only a small percentage of revenue to R and D, instead focusing on reverse engineering blockbuster drugs for international trade. The needs of the Indian and global pharmaceutical companies complement each other. Indian firms require large inflows of FDI and international companies need to significantly reduce R and D and manufacturing costs.

**Driving the move to offshore:** The current level of off shoring activities in pharma sector by advanced nations falls short in both scope and magnitude. But this is changing. There are four central factors altering the way pharmaceutical and biotech firms evaluate the sourcing of their operations. Expensive regulatory barriers and escalating cost pressures are motivating the pharmaceutical and biotech sectors to look past their conventional sites and cost differentials between high wage and low wage countries and time to market considerations are luring their operations to countries like China and India.

**Regulatory barriers:** The costly and restrictive regulatory regimes in the US, Western Europe and Japan are one of the primary drivers of off shoring.
Rising cost of R and D: The funding for R and D has been increasing hence the pharmaceutical companies have not been able to maintain past level of drug discovery. Each year requires more spending to produce same output around the clock on promising compound. On account of this the value of the outsourced pharmaceutical services industry is expected to double to approximately 55 billion USD by 2010. (Nerman Verawalla, 2006) Contract manufacturing and the outsourcing of clinical trials account for the majority of activity in this sector. The compelling need for capturing efficiencies and cost savings in developed nations has persuaded the pharmaceutical industry to follow the example of other industries that have elected to focus on core competencies and develop outsourcing relationships for non-core activities. Further there has been a sharp increase in the number of "virtual" pharmaceutical and biotechnology companies who seek to outsource all their manufacturing and clinical trial activities. (Nerman Verawalla, 2006)

6.4. Growth Opportunities in India

At present the pharmaceutical companies in India which primarily produce generic products are among the world's leading companies in this field. Since Jan 2005 India has demonstrated her intention on enforcing legislation to protect Intellectual property patents for both products and processes across a number of knowledge based industries.

The changes in the patent laws have prompted leading domestic companies to enter into business models. The first is to enter into regulated international markets with generics, formulating and specialty pharmaceuticals with a long term intention to develop their own new chemical entities. The second is to provide contract services to
international pharmaceutical companies in the field of contract services for drug discovery, chemical trials and manufacturing for marketed drugs. It is India's cost effective labour force and numerous government incentives that help to encourage the development of pharmaceutical contract services sector. As a result many top international pharmaceutical companies are accessing services from India. The services include contract research to support drug discovery, clinical trials and contract manufacturing. These are being conducted either via their own Indian local operating companies or via outsourcing alliances with local providers or the global vendors with Indian know how's.

6.4.1. Current Status of outsourcing to India

In the late 1980s and early 1990s multinational companies (MNCs) began to explore India's potential as a competitive research destination. This early wave consisted mainly of research laboratories those served their own manufacturing operations, the trend today is shifting to various models of contract research. There are three main areas in the pharma value chain where outsourcing takes place in India.

![The Pharma Value Chain](image)

Source Frost and Sullivan, 2008
The value chain is tentatively the path traversed from the discovery stage to the final marketing of a drug. The various stages are briefly being discussed with particular reference to the contract services presently made available in India. (Bain & Company, 2008)

6.4.2. Discovery Research and Contract Research

Drug discovery is an early yet highly intensive stage in the pharmaceutical industry. Activities in this stage include target discovery lead generation and lead optimization. In drug discovery Indian pharmaceutical companies are extremely strong in chemistry driven drug discovery activities such as organic synthesis, medical chemistry, process chemistry and analytical chemistry. India has witnessed a significant increase in the emergence of Indian division of MNCs providing drug discovery and development services. After recognizing the capabilities of Indian companies in this area and accessing the cost advantages several big pharma companies are experimenting to outsource their research and development processes to India. With the early phase drug discovery and chemical synthesis, global market at USD 4 billion, India currently at 0.7% (of total market) continues to grow at 40-50% per annum (Ernest and Young BPV, 2001)

6.4.3 Clinical Trials

Next to drug discovery, clinical trials constitute the most important stage. The clinical trial process includes many different phases (Phase I through IV) and include animal testing also. India offers right opportunity for swift meticulous and cost effective global clinical trials. Trial conduct because of stable regulatory environment. India
has about 350 million individuals residing in metropolitan cities that form the population base for clinical trial recruitment.

Due to relatively fewer competitor trials patient recruitment rates are rapid particularly than that of USA. India has both state subsidized and private health care system. Both the state and private hospitals in Indian cities have regulated patient attendant, motivated staff and equipment. Patient concentration at urban specialist sights improves the efficiency of clinical trials as site management and monitoring is streamlined.

Over the past few years India has been a key provider of high quality and cost effective bio-availability and bio-equivalence studies. The conduct of first in man studies for international sponsors continues to be restricted, yet local CROs offering bioequivalence studies have been successful in attracting business from international generic companies. Indian subsidiaries of global CRO industry composed of local CROs, Indian subsidiary of global CROs and data management providers is experiencing a local growth of 40%.(Ernest and Young BPV, 2001)

Currently there are more than 20 well established clinical trial organizations in India including a few global CROs which are offering Phase I-IV clinical trial services and are well equipped to comply with global standard such as ICH GCP guidelines. (Ernest and Young BPV, 2001) Around 80,000 clinical trials are being concluded globally each year. About 20-30% of global clinical trials are conducted in developing countries. In 2002 Indian clinical trial market of USD 32-35 million is projected to grow 8-10 times by 2010 to USD 250-300 million.
6.4.4. Contract Manufacturing

According to Pamitkar contract manufacturing is one of the most popular outsourcing concepts in the pharmaceutical industry at present. In India due to thriving generics formulation and bulk drug industry, world class synthetic chemistry skills and manufacturing facilities have been developed. Along with well developed chemistry and process innovation, skills are also developed due to years of fierce competition in the domestic generic fields. Thus India is able to offer services across contract manufacturing chain from custom chemical synthesis to API to formulations at a considerable saving and cost. (Ernest and Young BPV, 2001)

Outside USA India has the largest number of FDA approved pharmaceutical manufacturing plants and Indian companies account for 25-30% of total DMFs (Drug master Files) filed with USFDA. The labour cost for skilled chemist in India is considerably lower than the same in USA and western countries and in addition capital cost of building manufacturing facilities is 40% lower than the western Europe and North America. In 2005 India's share in total of USD 15 billion global contract manufacturing market was USD 100 million entirely comprised of API and intermediate manufacturing. By 2010 India's share is expected to increase to USD 1 billion of total USD 30 billion global market with 1/5th of revenue being accrued from the manufacture of formulation.

6.5. Conclusion

- Outsourcing make discovery to work faster and cheaper and reduces drug development costs.
- Reduces problems faced during the regulatory processes around the world
- Improves manufacturing efficiencies
- Reduces excess production capacity by divesting facilities
- Minimizes investments in capital-intensive facilities
- Improves net earnings and cash flow;
- Diverts resources to focus on other competencies like marketing

All these reduce the overall costs by 30-35%. (Haluska, 1997). Pharma multinationals have maintained a low-key presence in Indian market due to absence of product patents and rigid price controls. India today have largest number of US Food and Drug administration (USFDA) approved drug manufacturing facilities outside the USA and also due to amendment of Indian Patent Act in 2005 multinationals are strengthening their presence in the country. Outsourcing allows a pharmaceutical company to focus on its core competencies while contracting with external partners whose expertise complements their own. Under this arrangement, the ultimate benefit accrues to both the major pharmaceutical company and the partners. As the cost of pharmaceutical development continues to rise, more and more drug companies look to joint ventures as a means to capitalize on the complementary strengths of the other partner, and outsourcing critical processes becomes an important strategic step. These relationships occur between large, established companies, between large firms and smaller companies, and even between start-up firms (such as biotech companies) and small, specialized outsourcing companies. In other words, client companies buying outsourcing services can be big or small, and firms providing outsourcing services can, similarly, be big or small. The important consideration is that one of the partners faces limited capabilities and seeks to acquire additional services from another firm (Haluska, 1997).
Pharmaceutical companies outsource in an effort to maximize speed and efficiency, but the more they outsource, the more numerous the claims the outside firms can make on any eventual profit.

Another cost of outsourcing is the risk of becoming too dependent on other firms. With many outsourcing arrangements, buyers lose their independence and are forced to rely on firms whose long-range strategic interests might not be closely aligned with those of the contracting firm (Reilly 2000).

6.5.1. Main benefits of off shoring

To reputed and large pharmaceutical companies drug discovery and clinical processes are very sensitive and vital operations. For outsourcing these operations they are a bit curious of the correctness and management of the entire operations. There is very little tolerance for errors and simple mistakes compromise results, and in some remote cases harm patients, resulting in a very large and expensive liability. Russ Bamitam of Pharmaceutical Research and Manufacturers of America (PhRMA) observes that misreading, losing or misentering one piece of data could result in a billion dollar lawsuit. A drug when it is ready is required to be approved by authorities in different countries when the drug approval authorities FDA in case of USA. If the authorities find flaws in any aspect of pharmaceutical research, companies face set backs. If these errors are found while drug is out on market, it can result in loss in billions. Relying on foreign vendors and partners can make compliance more burdensome and risky.

In outsourcing, partners should have an element of trust in each other and the problems get magnified if partners do not know each other well. In case of an
unsuccessful partnership, loss is not only financial but also of time and opportunity. In outsourcing arrangements there is also a partial loss of control as it passes from client to provider. As a result the information available to project manager is less detailed if it had been retained in house.

Many firms may be unduly harassed about the protection of intellectual property rights during outsourcing. If the information is leaked to competitor or generic manufacturer, the only recourse a firm can take is through legal system. If outsourcing is done to a number of vendors, there is challenge to juggle with a number of individuals at different places. Even with so many risk factors involved optimistic pharmaceutical companies are outsourcing both routine and core functions.

Rules and regulations regarding pharmaceutical products and services differ from country to country and services from India may not find approval in some over regulated market, thus being barriers to entry and growth. Doctors in India in general have excellent skills and patient coverage but not so proficient in GCP trials. An international company may carry out phase I trial, concurrently. After submission of phase I data generated outside India, sponsors may be permitted to repeat phase I trials, Phase II, III and IV trials can be concurrently done with other global trials, for that drug.

An import of body fluids /test samples from India has been another difficulty hampering the industry. Companies that have global testing labs for sample testing faced failures in the outsourcing strategy due to this and lack of world class GLP labs further prevents these companies from successfully completing their trials.
There are instances of unethical trials without requisite permissions or on ill-informed patients. A recent survey of 200 health researchers globally that was commissioned by the former U.S. National Bioethics Advisory Commission and published in February edition of Medical ethics revealed that a quarter of clinical trials conducted in developed countries did not undergo ethical review. Local disinformation campaign can also spoil clinical studies and damage companies reputations. (Vyas Jay Narayan and Shah Gitesh, 2000)