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REASONS FOR OUTSOURCING IN PHARMACEUTICAL INDUSTRY

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ABSTRACT

Pharmaceutical companies have to undergo a lot of research and development activities prior to releasing a new drug. They also need to conduct clinical trials prior to getting's nod for releasing drugs into the market. Large companies tend to outsource their non-core activities to third party service providers who can carry out these activities cheaply. The most common forms of pharmaceutical outsourcing are CROs contract research organization and CMOs contract research manufacturing. This involves R&D outsourcing and manufacturing of medication such as pills, tablets, capsules, etc. This is beneficial for both large multi-national pharmaceutical companies as well as smaller ones. By outsourcing their non-core activities to third party service providers, the pharmaceutical companies can concentrate on the drug discovery and focus on other competencies like marketing their new drugs. The study included of about 40 pharmaceutical R & D outsourcing companies. Survey was conducted from 2009 to 2012. Out of 40 pharmaceutical outsourcing companies, 25 pharmaceutical R & D outsourcing companies were from India and remaining 15 pharmaceutical R & D outsourcing companies were from outside of the India mostly from USA.

Keywords: R & D Outsourcing, Pharmaceutical industries, CROs, CMOs, Cost Saving, Time Saving.

INTRODUCTION

"A company which assigns some of its non-core activities to third party is known as outsourcing". Outsourcing is an important activity preformed in the pharmaceutical companies which provide essential information regarding how essentially things are done rather than what is to be done. The process by which an organization contracts with another individual or company to get some of its work done is known as outsourcing. Normally it is non-core aspects of the business that are outsourced. Outsourcing plays an important role in pharmaceutical industry in cost cutting, time saving so that they can concentrate on their Core Competencies such as drug discovery and marketing their new drugs. Outsourcing is the current mantra used pharmaceutical industry. Outsourcing can be performed not only in drug discovery, manufacturing, packaging,

sales & marketing of the products but also in clinical trials. By Outsourcing it involves reducing the scope, defining quality levels, re-pricing, re-negotiation, and cost re-structuring. Long time back pharmaceutical industries used to build all the products internally and they did not encourage the third party service providers. However the situation has been changed the in-house resources are getting exhausted with a very thin product pipeline and in addition many drugs are going off patent by 2008 hampering company sales and competitiveness [2]. It takes \$800 million and 20 years for a new drug/device to enter the market. Patient recruitment and medical personnel account for nearly 70 per cent of the clinical costs that are required to bring a drug to market. Threat from generics, low productivity of R&D process, higher costs for product approval and parallel imports are the major market feature for decreasing pharmaceutical

profits. Global outsourced R&D expenditure is increasing every year leading to rise in business prospects for Contract Research and Manufacturing services. Nearly out of 10,000 molecules developed in laboratories only one or two are likely to pass successfully through the all stages of drug development and be commercialized which was estimated by The European Federation of Pharmaceutical Industries and Associations (EFPIA). These are reasons for the pharmaceutical companies to go for outsourcing to developed countries. Normally for R & D the option is Contract research organizations and for manufacturing the option is Contract manufacturing organizations [3].

The opposite of outsourcing is called insourcing which entails bringing processes handled by third-party firms in-house, and is sometimes accomplished via vertical integration. However, a business can provide a contract service to another business without necessarily insourcing that business process.

Advantages of pharmaceutical outsourcing

1. Cost saving: Taking into consideration the huge costs involved in developing a new drug, pharmaceutical companies can save a lot of money by outsourcing some part of their activities to third party vendors. Let's consider an activity that is a part of pharmaceutical R&D – Clinical trials of experimental drugs. This activity requires the right kind of patients – who are healthy on the whole but have one ailment, which the drug attempts to cure. And most importantly, these patients must be willing to subject themselves to experimentation. For a small or medium-sized pharmaceutical company, this could involve a lot of trouble. Whereas, by outsourcing this task to a specialized vendor, they can do this at a lower cost as well as save a lot of time and effort. Outsourcing reduces the overall costs by 30% to 35%. [1]

2. Time saving: By outsourcing routine tasks such as R & D, bulk manufacturing, the pharmaceutical company can save its time for important tasks such as new drug research. Thus, pharmaceutical outsourcing has numerous benefits for pharmaceutical companies. [1].

By outsourcing one can do the work faster because there won't be any beurocracy. In big companies there will be more departments and different levels of hierarchy. For any approval of a project it has to cross different departments to get the approvals obviously it will take lot of time. In outsourcing there won't be such type of problems. The work will be completed faster and cheaper because there will be lot of competition among the service providers [2].

3. Focus on Core Competencies: By outsourcing the non-core activities such as R & D, bulk manufacturing, pharmaceutical companies can concentrate on their core competencies such drug discovery, marketing of their drugs.

4. Operational expertise: Sometimes clients won't be having a person who has technical knowledge. Then by outsourcing the will take help of third party service provider who has specified knowledge which the clients requires. Offshoring can give you access to professional, expert and high-quality services.

5. Less Capital Investment: By outsourcing the pharmaceutical companies can give their projects to third parties vendors to save their capital investment.

Review of Literature

India now second only to US as our study were also correlated with the other studies carried out by, R&D powerhouse. The article reports that India is emerging as a powerhouse of pharmaceutical R&D. Backed by a scientist president and with an army of talented scientists, the country now has R&D capacity second only to the US, at one-fifth of the cost. In this article the author also pointed out the statement said by Dr Brian Tempest, chief mentor, Ranbaxy Laboratories, at last week's Economist pharmaceuticals conference. "India is now the third most popular location for R&D investment and has plans to develop itself further from within as the number of original domestic institutions begins to evolve, "Cost savings are sometimes as great as 85 per cent on R&D conducted in the West, and India has the highest number of FDA-approved drug manufacturing plants outside the US."No other country compares,""From a US point of view, Indian chemists are seen as 30 per cent better educated and work nearly 50 per cent longer weeks for 20 times less,""15 per cent of staff in the US pharmaceutical industries laboratories is now Indian,"[4].

"Drug R&D is increasingly outsourced to India" The objective of the article is to bring out the facts that western countries are outsourcing their products to Indian CROs. The author was expressing India's reputation as a hub for pharmaceutical research and development (R&D) was growing. The country's drug industry was famous for its skill in copying products developed elsewhere, but Indian companies, prompted by new patent laws, have begun discovery programs of their own and set their eyes on the global market for innovative drugs. The author also pointed a comment in his article raised by Enrico Polastro, vice president of global management consultancy firm Arthur D. Little. that "There are Indian companies that are engaged in the discovery of their own products, and are offering these for licensing to third parties, even at very early stages". The author also explained in his article that leading Indian CROs such as Nicholas Piramal, Dr. Reddy's Laboratories, and Ranbaxy, which have spun off their discovery divisions in an effort to capture the interest of Western companies. The author concludes that India is pushing into fresh territory by evolving from a commodity-driven drug market into a research-driven development centre [5].

“Opportunities Beyond Cost Savings- Maximizing the Strategic Value of Global R&D Outsourcing” Published in Contract Pharma Magazine. The objective of the article was, the US based pharmaceutical companies will enjoy cost-saving benefits if they outsource their R & D to third party service providers. Due to outsourcing the pharmaceutical Industries could save upto one third of the total cost of the project. Several large multinational pharmaceutical companies have announced plans to double if not triple the percentage of the work that they currently outsource. Companies such as Pfizer, which currently outsources 15% percent of its R&D to other countries, will be planning to double that amount, AstraZeneca and GlaxoSmithKline has plans to dramatically increase their R&D outsourcing activities. Western companies such as Merck are going to have partnership with India's Piramal to conduct preclinical research and Eli Lilly will be entering into an agreement with China's Hutchinson Medipharma to conduct R&D activities in the area of oncology.

The author also predicting that the market for overseas R&D outsourcing is believed to be close to \$12 billion. At the current annual growth rate of nearly 15%, the market for overseas R&D outsourcing in 2014 could be as much as \$33 billion [6].

“Outsourcing Pharmaceutical R&D” published in Career Advice. The objective of the article was how American pharmaceutical companies have been intermittently laying off thousands of employees for the past two years or so. Many of the employees who have lost their jobs are R & D scientists, marketing personnel and sales representatives. Fewer drugs are being discovered and brought to market; fewer people are required to market and sell them. By taking their cues from the IT and software industries, many US drug makers are beginning to either transfer R&D operations to foreign, company-owned research facilities or outsourcing some or all R&D activities to foreign contract research organizations (CROs)

The author was trying to explain that due to outsourcing, India and China were manufacturing a majority of the active pharmaceutical ingredients (APIs) and excipients found in many drug sold in the US. The increasing cost in US R & D pharma companies were outsourcing to India & China. In this article the author mentioned that BMS is expanding its R&D operations in Bangalore, India. The author concluded that how US based pharmaceutical companies will sustain in the business if they continue to lay-off employees who are seemingly responsible for developing new sources of revenue for them? “America’s loss is India’s gain!” [3].

Big Pharma Begins Outsourcing Research and Development”, the objective of the study is to bring out the facts how pharmaceutical industries are outsourcing their R & D. The pharmaceutical companies are cutting back on in-house research and development (R&D). They

are concentrating on their core -activities such as drug development and others. The author also explained that Big Pharma’s Outsourcing Deals such as Eli Lilly, Sanofi-Avantis, Glaxo SmithKline outsourcing to third party service providers. Eli Lilly had 10 year agreement with Convance in 2008, Sanofi-Avantis had agreement Sanofi’s Porcheville, France and Alnwick, UK R&D productivity sites and GlaxoSmithKline has taken up the trend too. It is moving 14 researchers and several patent rights to Convergence Pharmaceuticals, in exchange for an 18% equity stake. Company like GSK normally handles 200 molecules a year, now they are handling 2000 molecules per annum due outsourcing. The author also explains the large companies hope to cut down R & D costs that why, boosting productivity. He also explained that most investors also know by now that many big pharmaceuticals face impending patent expiry on existing products. So those companies are now restructuring, including outsourcing of both clinical services and research in order to boost productivity [7].

R & D Outsourcing, “With all of the demands on pharmaceutical companies today to be more efficient and compliant with regulations, research and development (R&D) organizations are choosing to use external service providers increasingly to help relieve the burden”. The objective of the study was that pharmaceutical companies were outsourcing their non-core activities to external service providers so that they can cut down their cost up to 30 % to 60 % in countries such as India and China, which have high number of science professionals. The author also explains that companies do not always have a regulatory presence in every region in which they do business, a single partner that can manage activities across multiple markets is an attractive proposition. The author concludes that the drive to cut costs, meet shareholder demands, bring products to market more rapidly and improve product pipelines means outsourcing is likely to become an increasingly important part of R&D business. Making it work just requires good planning. He finally concluded that carefully selected external service providers can be cost-effective and relieve the pressure on firms looking to streamline operations [8].

“R&D outsourcing set to climb”. The objective this article was to bring out the reasons behind 15 per cent rise annually. By means of outsourcing clinical trials can be done cheaper, faster and more efficient. The author was also pinpointed in the research that “Another attraction of outsourcing clinical development is that it can be implemented relatively quickly,” and the main drivers of the growing appeal of outsourcing for pharmaceutical companies, which include the reduction of financial risk by limiting in-house investment, the chance to save significant time and money while improving quality and speed, and the opportunity to get approval in several countries at the same time by using an international contract research organisation (CRO). The offshoring

clinical trials to emerging markets around the world are increasingly seen as a very attractive alternative. As a result, CROs have received the lion's share of outsourced clinical research revenue and are now extending their offering to international levels. The author concludes that Outsourced pharmaceutical R&D spending is set to increase at twice the expected rate of general R&D expenditure for the next five years [9].

“Pharma Outsourcing on Upward Trajectory”. The objective of the article was that apart from Cost savings companies also outsource to boost technology, benchmark internal programs, and to speed up the process. The author conveyed that over the past two decades, however, the outsourcing pattern has changed as companies began routinely outsourcing a number of core functions such as clinical trial management and manufacturing. Drug discovery was one of the more recent core functions to be outsourced. The industry is choosing to outsource core drug discovery functions more frequently. Issues over loss of control, intellectual property, and confidentiality remain a concern for some companies, but in many cases companies and CROs are addressing these issues in improved strategic partnerships. By outsourcing portions of their drug discovery programs, many pharmaceutical and biotechnology companies have found an effective cost-cutting strategy that can also improve the hit-to-lead conversion and early identification of unsuccessful compounds. Countries such as China and India are the major countries to which drug discovery is being outsourced. Both have significant scientific expertise, a cost advantage (due to lower wages and in some cases, significant tax incentives), and the infrastructure needed to successfully perform drug discovery activities. Russia and the Ukraine also have a growing presence in the drug discovery outsourcing market. The author concludes that “Desire to Save Money, Boost Technology, and Speed Discovery Process Drives Growth” [10].

Objectives

- To identify the reasons for outsourcing in pharmaceutical industry
- To examine the advantages of pharmaceutical outsourcing

Hypothesis

Whether outsourcing benefits pharmaceutical industries?

Methodology

- Data Collection Method
- Data Collection Method
- Source of the Data

The study depends on primary and secondary source.

Primary Source

- Direct personal investigation in the form of the questionnaire.

- Indirect oral investigation in the form of interview.

The data has driven mostly by R & D heads such as Managing Directors, Directors, Chief Executive Officers, Vice Presidents, Assistant Vice Presidents, General Managers, Assistant General Managers and managers. Normally Managing Directors, Directors, Chief Executive Officers were responsible selection of projects.

Secondary Data

Secondary Data will be driven from,

- Books
- Journals
- Company Records
- Company Web Sites

Sampling Techniques

Two different techniques were used in this study, they are,

Simple Random sampling

Simple Random technique was adopted to choose the Pharmaceutical R & D outsourcing companies. This technique was used to keep in view the scope of the study which tries to cover different Pharmaceutical R & D outsourcing companies.

Systematic Sampling

The other technique which we used was systematic sampling. Here from the list of Pharmaceutical R & D outsourcing companies. We randomly picked some of the pharmaceutical R & D companies which were into outsourcing, their products to third party service providers.

Research Design

As this study aims to find out reasons for outsourcing in pharmaceutical industry and how the Outsourcing will be going on in pharmaceutical R & D companies.

Survey Instrument and Questionnaire

In order to gather the information from the research participants of the 40 pharmaceutical companies the questionnaire method was adopted, the questionnaires were developed in consultation with my Research Guide, my MD and my colleagues.

Data Collection and Field Work Plan

25 Pharmaceutical Industries located within India and 15 Pharmaceutical Industries located mostly in USA.

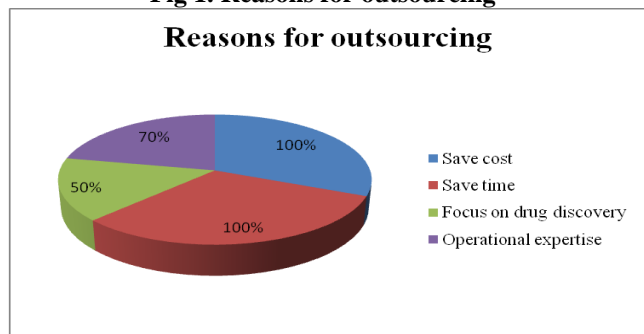
Research Design

Sample Size

For the purpose of the study, a sample of 40 pharmaceutical R & D outsourcing companies taken into consideration, 25 pharmaceutical R & D outsourcing companies taken out of which there 10 pharmaceutical

companies they were into blend of both R & D outsourcing and R & D in sourcing within the India and 15 pharmaceutical R & D outsourcing companies taken from outside of the India mostly from USA.

Fig 1. Reasons for outsourcing



RESULTS

It is evident that different companies were representing reasons for outsourcing their products. Out of 40 selected companies, 100 % of companies were showing to save cost & to save time, 50% of the companies were showing on focus on drug discovery and 70 % of the companies were showing on operational expertise.

DISCUSSION AND CONCLUSION

We would like to conclude that Outsourcing in Pharmaceutical Industries plays an important role not only in cost cutting, time saving, focusing on drug discovery, manufacturing, packaging, sales & marketing of the products but also in clinical trials. It provides a big support to pharmaceutical and biotechnology industries for completion of their projects hassle free.

Table 1. Reasons for outsourcing

Particulars	Number of Companies	Percentage
Save cost	40	100
Save time	40	100
Focus on drug discovery	20	50
Operational expertise	28	70
No of Companies To Be Studied	40	100

Out of 40 Companies, number of companies responded for each aspect.

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