

REASONS FOR CHOOSING CONTRACT MANUFACTURING ORGANIZATION IN PHARMACEUTICAL INDUSTRY

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ABSTRACT

During our survey from 2009 to 2012 we had found some different issues regarding outsourcing in Pharmaceutical companies which were beneficial and non-beneficial for large multi-national pharmaceutical companies as well as smaller ones, other side of our study we had found there were some advantages of Contract Manufacturing Organization in Pharmaceutical Industry. The study included of about 40 pharmaceutical outsourcing companies. Survey was conducted from 2009 to 2012.

KEYWORDS: Contract Manufacturing Organization (CMO), Outsourcing, Pharmaceutical Industries, Food and Drug

Administration (FDA).

INTRODUCTION

“A company which assigns some of its non-core activities to third party is known as outsourcing”. Outsourcing is an important activity performed 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 will save time, which is often critical because any delay in production processes, batch releases, or obtaining approvals from regulatory bodies can severely damage a company's prospects. 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.

By way of outsourcing some of the client's faces some hurdles with third party service providers such as communication barrier, threat to intellectual property rights, quality problem, etc. Though cost is one issue which is important factor; however there are two other critical factors such as intellectual property and quality & safety issues. Of these the most important one is intellectual property rights. Some of the third party service providers selling their clients patents rights to other companies and manufacture & sell drugs that rightfully belong to someone else.

The Food and Drug Administration issued approvals for 12,000 plants in India and China. The employment in American pharmaceutical industry came down 5 percent from the last year and India's pharmaceutical industry grew 13 percent in case of hiring employees. According to EconomyinCrisis.com, 1,742 drugs were recalled in 2009 and just 338 drugs were recalled in 1999 due to outsourcing. Even the simple over-the-counter drugs have been recalled because of safety concerns, including Proctor & Gamble Decongestant Nasal Spray and Johnson & Johnson's Children's Tylenol, Tylenol Arthritis Pain Caplets, Extra Strength Tylenol Rapid Relief Gels. The latter was traced to a fungicide that originated from a Puerto Rican plant.

While some of those products were manufactured in the U.S however their components came from outside the U.S., and due to the lack of manpower at the FDA, much of it goes unchecked until a problem is discovered. "Up to 40 percent of the drugs Americans take are imported, and up to 80 percent of the active pharmaceutical ingredients in those drugs come from foreign sources," Food and Drug Administration Commissioner Margaret Hamburg, M. D., said, according to *The Buffalo News*.^[1]

A Contract Manufacturing Organization (CMO) is otherwise known as Contract Development and Manufacturing Organization (CDMO). CRO is meant for research & development and CMO is meant for manufacturing.

Services offered by CMOs are follows,

Pre-formulation, formulation development, stability studies, method development, pre-clinical and Phase I clinical trial materials, late-stage clinical trial materials, formal stability, scale-up, registration batches and commercial production.

EVOLUTION OF CMO

In the pharmaceutical industry, if R & D has to outsource that can be provided through contract research organizations (CROs) and for outsourcing manufacturing than contract manufacturing organizations (CMOs). Now a day contract development and manufacturing organizations (CMOs) is coming if any pharmaceutical company is looking for a comprehensive single-source provider from drug development through commercial manufacture.^[2]

ADVANTGES OF CONTRACT MANUFACTURING ORGANIZATION

1) Cost Saving

Taking into consideration the huge costs involved in plant and equipment, the pharmaceutical companies can save a lot of money by outsourcing some part of their activities to third party vendors. Outsourcing to CMO's can reduce the overall costs by 30% to 35%.

2) Focus on core competencies

Outsourcing to a CMO allows the pharmaceutical client to expand its technical resources without increased overhead. The client can then manage its internal resources and costs by focusing on core competencies and high-value projects while reducing or not adding infrastructure or technical staff. Virtual and specialty pharmaceutical companies are particularly well-suited to CDMO partnerships, and big pharmaceutical companies are beginning to view relationships with CDMOs as strategic rather than tactical.

3) Less Capital Investment

Working with a CMO also limits a client's upfront capital investment for drug development, thus minimizing a project's cost. By concentrating resources with a single-source provider, the outsourcing client can minimize technical transfer of projects or products, thereby reducing unforeseen costs and potentially speeding new products to market.

4) Geographic Advantage

If the CMO is located in another country and if it is in close vicinity with the API supplier, it will provide tremendous logistical savings.

5) Flexibility

Based on the current business trends, work scheduling can be reshuffled easily without affecting work on other products.^[3]

REVIEW OF LITERATURE

Our study were also correlated with the other studies carried out by, Dustin Ensinger's objective in his article "Pharmaceutical Outsourcing threats" was the U.S. pharmaceutical industry is no longer immune to the outsourcing phenomenon, which poses major risks for American consumers. The author specifies India is becoming a major destination for American pharmaceutical companies seeking to boost their bottom line. Taking their cues from other American multinational corporations, they are doing so by outsourcing their manufacturing to the Indian subcontinent according to *The New York Times*. The author also pointed a comment in his article raised by Panos Kalaritis, the chief operating officer of Irix Pharmaceuticals, a Florence, S.C., contract research and manufacturing company, that "Cost is one issue, and yes it is important, but there are two other critical factors: intellectual property and quality and safety issues," in *The New York Times*. He has mentioned that Americans were losing jobs and Indians were gaining jobs due to outsourcing. The employment in American pharmaceutical industry came down five percent from the last year and India's pharmaceutical industry grew 13 percent in case of hiring employees. The Food and Drug Administration issued approvals for 12,000 plants in India and China. He has mentioned the quality issue where last year, 1,742 drugs were recalled and just 338 drugs were recalled in 1999. Even the simple over-the-counter drugs have been recalled because of safety concerns. Even some of those products were manufactured in the U.S however their components came from outside the U.S., and due to the lack of manpower at the FDA, much of it goes unchecked until a problem is discovered.

"Up to 40 percent of the drugs Americans take are imported, and up to 80 percent of the active pharmaceutical ingredients in those drugs come from foreign sources," Food and Drug Administration Commissioner Margaret Hamburg, M. D., said, according to *The Buffalo News*.^[1]

Daya Mukherjee was insisted in his article that "Look Before You Sign Your Outsourcing Contract" He explained the factors that a firm needs to look for before signing the outsourcing contract. He explained clearly that the contract should typically cover scope of work, little flexibility in the contract, problem resolution such as monetary compensation,

problem escalation, terminating the contract procedures, repatriation clause etc., terms & conditions agreed upon, the service level agreement, and non-disclosure agreement should signed by both the parties.^[4]

Mak Jawadekar was sharing his experiences in his article “Outsourcing Steps in India-The biggest advances in the Indian CMO arena” which was published in contractpharma.com. The author was sharing his experiences at some partnership meeting with many Indian companies during the Bio Asia 2009 Conference in Hyderabad with Pfizer's senior management - including two Presidents of Pfizer Global R&D (Dr. John LaMattina and Dr. Martin Mackay. He also had had a meeting with the President of India, Mrs. Pratibha Patil. She was very interested in knowing how global pharma companies like Pfizer could help patients in India get access to the modern medicines.

A rising global acceptance of generics, coupled with increased outsourcing of manufacturing by "Big Pharma" to lower-cost locations, has benefited the export-focused Indian pharma companies. The author was predicting that contract manufacturing volumes outsourced to India, as well as certain partnerships and alliances by multinational companies (MNCs) with quality Indian majors will increase. He was giving example of Aurobindo Pharma and Claris Lifesciences have entered into alliances with large pharma for specific products, including upfront license fees.

He was pin pointing that India-focused pharma companies will continue to benefit from steady domestic growth, with a consequent overall boost in volumes and capacity utilization. Pricing pressures - due to a greater-than-expected increase in competition - could offset some of the anticipated improvements in profitability. He showed the difference between existing players as well as new entrants into the generics space. This will lead to key risk factor for future margins. Even regulatory issues could also have an impact, primarily with regard to approvals for new products and any tightening in quality controls. The author was saying that India is well-placed in strong manufacturing base - both in formulations, as well as in key areas (bulk drugs and APIs). India has the highest number of FDA-approved plants outside of the U.S. Many global financial firms have predicted that rising purchasing power and increasing penetration of health insurance reform will support strong growth in India's domestic formulations business in the long term.

Makarand (Mak) Jawadekar most recently served as Director, Portfolio Management and Performance at Pfizer Global R&D, until February 2010, when he opted for an early retirement after 28 years at Pfizer Inc. He currently serves on several companies' advisory boards and also consults with bio/pharmaceutical companies for global outreach in emerging market regions.^[5]

“Global Pharmaceutical Contract Manufacturing Market to Reach US\$40.7 Billion by 2015” published in PharmaManufacturing.com, 2011. The author in this article conveyed that the global market for pharmaceutical contract manufacturing witnessed robust growth in recent years, and the future continues to hold tremendous prospects for the industry. Several developed countries in the globe began scouting for ways to minimize expenditure on drugs. Most of the pharmaceutical companies were trying to minimize cost of drugs which directly lead to evaluate opportunities for manufacturing outsourcing.

Even at the time of recession the pharmaceutical contract manufacturing industry, overall market maintained a positive growth posting only a moderate slowdown in growth. However, a drop in venture capital funding due to the recession has compelled many pharmaceutical and biotechnology companies to cut down on spending, affecting the fortunes of contract manufacturers worldwide. This resulting to several projects were kept on hold and new project starts were delayed, cascading the impact of the pharmaceutical industry to the outsourcing industry as well.

The author emphasizing manufacturing capacity constraints are only one of the reasons for outsourcing. Pharmaceutical manufacturing entails sophisticated technology (cGMP synthesis and scale up, impurity profiling, lyophilization) and strict regulatory compliance (good manufacturing practices - GMP). Outsourcing such activities to Contract Manufacturing Organizations (CMOs) enables a pharma company to expedite its R&D, and thus realize the potential revenues. Moreover, CMOs are increasingly offering a wide range of value-added services, which make PCMO an indispensable opportunity to pharma companies.

The author listed major players profiled in the report include Althea Technologies, Catalent Pharma Solutions, Dishman Pharmaceuticals and Chemicals Ltd, HAUPT Pharma AG, Jubilant Life Sciences Limited, Kemwell Pvt. Ltd, NextPharma, Nipro Corp., Patheon Inc., Royal DSM N.V., among others.^[6]

Ed Silverstein in his article “Pharmaceutical Contract Manufacturing Vendors See Increases in Revenue”, healthtechzone.com, 2013 published in h.healthtechzone.com was referring the quotation led down by Frost & Sullivan “The market for pharmaceutical contract manufacturing earned \$13.43 billion in revenue during 2012 and it may go as high as \$18.49 billion in 2017” The article also noted that how pharmaceutical companies concentrate on “core competencies,” which has led to more outsourcing and helped the pharmaceutical contract manufacturing market. The sector includes: injectable doses, liquid doses, semi-solid doses and solid doses.

The author conveyed the statement led down by Frost & Sullivan analyst Aiswariya Chidambaram “Investments and capacity expansions in the injectable dose formulation segment are in the near future, as it is likely the most significant source of income for the global pharmaceutical contract manufacturing industry,” and “Cytotoxics manufacturing, in particular, offers immense growth potential, given the demand from the cancer research and therapy segments.”

In this article the author noted that the analysis done by Frost & Sullivan that how the pharmaceutical contract manufacturing market is “highly fragmented with many contract manufacturing organizations (CMOs) relying on one client for more than 50 percent of their revenue.”

“Coupled with huge tax incentives and lower inventories for low-volume products, this creates immense pricing pressures for CMOs,” the firm said in a statement.

The United States and Europe are major markets for outsourcing finished dose formulations and sterile preparations, Frost & Sullivan said.

The author has given example of a U.S.-based company is Pharma Tech Industries (PTI), a contract manufacturer and packager. It is believed to be largest contract processor and packager of powder products. It makes over one billion effervescent tablets a year, “moves over 50 million pounds of powders yearly, and the numbers for their cotton swab and injection molding production lines are equally large,” according to a report from Advantage Business Media.

In addition, Asian CMOs are often used for active pharmaceutical ingredients, intermediates and generics. Also, because of lower costs, Asian CMOs, such as in China, India and

Singapore, could become “favorable destinations, particularly for solid dose formulations,” Frost & Sullivan said.

Watch out for more acquisitions and alliances in the sector, too.

"Consolidation in the form of acquisitions and strategic alliances to gain access to new, emerging markets and niche segments will be crucial for both small and large CMOs," Chidambaram predicts. "Large CMOs can broaden their geographic presence, while small CMOs can leverage the technical expertise and resources of large CMOs to enlarge their footprint."^[7]

Aiswariya Chidambaram/Frost in their article “Contract manufacturing to reach \$18 bn by 2017” published in Biospectrum.com, 2013 was specifying that “Global pharmaceutical contract manufacturing market earned revenue of \$13.43 billion in 2012 and is estimated to reach \$18.49 billion in 2017”, expanding market for solid dose, liquid and semi-solid dose and injectable dose formulations, according to a report by Frost and Sullivan.

According to the analysis firm, cost benefits and pharmaceutical companies' desire to focus on their core competencies has created an increasing need for outsourcing and spurred the global pharmaceutical contract manufacturing market.

The analysis firm also specifying that expiring blockbuster drug patents will reduce manufacturing capacity utilization rates and leads to outsourcing further.

The source of income for the global pharmaceutical contract manufacturing industry would be expansion and investments in the injectable dose formulation segment are in the near future the analysis firm healthcare research analyst, Ms Aiswariya Chidambaram confirms.

Cancer drugs manufacturing gives growth potential and demand from cancer research and therapy segment. The global pharmaceutical contract manufacturing market remains highly fragmented with many contract manufacturing organizations (CMOs) relying on one client for more than 50 percent of their revenue.

Coupled with huge tax incentives and lower inventories for low-volume products, this creates immense pricing pressures for CMOs,” The analysis firm insisted that Currently, the US and Europe are major markets for outsourcing finished dose formulations and sterile preparations, whereas Asian CMOs are preferred destinations for active pharmaceutical ingredients,

intermediates and generics. However, due to the immense cost benefits, Asian CMOs, like in India, China and Singapore, will likely emerge as favorable destinations, particularly for solid dose formulations.

"Large CMOs can broaden their geographic presence, while small CMOs can leverage the technical expertise and resources of large CMOs to enlarge their footprint." Ms Chidambaram concluded.^[8]

OBJECTIVES

1. To identify the reasons for choosing CMO in Pharmaceutical Industry.
2. To examine the advantages of CMO in Pharmaceutical Industry.

HYPOTHESIS

Whether outsourcing to CMO's are beneficial to the pharmaceutical industries?

METHODOLOGY

Data Collection Method

The study depends on primary and secondary source.

Primary Source Data

Primary data has been collected through the direct personal investigation in the form of the questionnaire and Indirect oral investigation in the form of personal interview.

Secondary Source Data

Secondary Data will be driven from, books, journals, company records, company web sites.

RESEARCH DESIGN

Research design means the basis of defining the research problem. The preparation of the design of the research project is popularly known as the research design. The study aims to find out the reasons for choosing Contract Manufacturing Organization in Pharmaceutical Industry.

Sample Design

For the purpose of the study, a sample of 40 pharmaceutical outsourcing companies taken into consideration, 25 pharmaceutical outsourcing companies taken into consideration of which 10 pharmaceutical companies were into blend of both outsourcing and in sourcing

within the India and 15 pharmaceutical outsourcing companies taken from outside of the India mostly from USA.

RESULTS

40 Different companies were representing for advantages of CMO in pharmaceutical outsourcing. 100 % of companies were showing for Cost Saving & for Focus on Core Competencies, 75 % of companies were showing for Less Capital Investment & Geographic advantage and 70 % of the companies were showing for Flexibility.

Table 1. advantages of contract manufacturing organization.

Particulars	Number of Companies	Percentage
Cost Saving	40	100
Focus on Core Competencies	40	100
Less Capital Investment	30	75
Geographic advantage	30	75
Flexibility	28	70
No of Companies To Be Studied	40	100



Figure 1. advantages of contract manufacturing organization.

DISCUSSIONS AND CONCLUSION

Based on our study we would like to conclude that outsourcing to CMO's in pharmaceutical industries plays a significant role not only in Cost Saving, Focus on Core Competencies, Less Capital Investment and Geographic advantage but also in Flexibility. It provides a big support to pharmaceutical and biotechnology industries for completion of their projects hassle free.

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