



International Journal of Pharmaceutical Development & Technology

www.ijpdt.com

e ISSN - 2248 - 910X

Print ISSN - 2248 - 9096

CONTRACT MANUFACTURING – A NEW ERA IN PHARMACEUTICAL MANUFACTURING

Bhavini Lad*, Krishna Joshi, Kuntal Goswami, P.K. Pradhan, U.M. Upadhyay

Department of Pharmaceutical Quality Assurance, Sigma Institute of Pharmacy, Bakrol-390019.

ABSTRACT

Contract manufacturing involves production of goods by firm, under the label or brand of another firm. Contract manufacturers provide such service to several firms based on their own or consumers' designs, formulas, and or specifications. The pharmaceutical industry is big on contract manufacturing. The reason is that buying equipment to mass produce certain chemicals is very costly. And some companies can't do it. So they enter into a contract with a manufacturer to produce certain chemicals for them so they can combine those chemicals with what they have to produce the end result. When working with contract manufacturing there are benefits and risks. When making the decision on whether or not a company should contract manufacture, the company should weigh the benefits and risks associated with it. Contract manufacturing works if the company gets involved with the right company. If the company were to get involved in the wrong company, the whole process will not work. Mostly contract manufacturing benefits companies who want to give their customers goods or services only they can provide, but using another company to provide or produce the goods, thereby lowering costs. By using contract manufacturing, a company can contract with various companies to sell their products, while saving on costs.

Key Words:- Contract manufacturing, Cost, High quality, Benefits, Risks.

INTRODUCTION

If somebody owns or operating a pharmaceutical company that releases prescription and over-the-counter medications, then they might want to find contractors that can help you keep your costs low without reducing the high quality which will attract more customers [1]. Operations & Production having another firm produce product or part or the outsourcing of a requirement to manufacture a particular product or component to a third party. Contract manufacturing enables companies to reduce the level of investment in their own capabilities to manufacture, while retaining a product produced to a high quality, at a reasonable price, and delivered to a flexible schedule.

The use of contract manufacturers means that the hiring firm does not need to purchase expensive manufacturing facilities, equipment, machinery, raw materials or hire specialized labor. This not only allows the hiring firm to focus solely on sales, advertising and marketing, it allows a firm that is comparatively more efficient at manufacturing to carry out the process. As a result, hiring firms often benefit from economies of scale and the purchasing power of large manufacturers. All of these factors lower production costs [2-5].

Pharmaceutical contract manufacturing can include a variety of services, so one should carefully weigh their options before making a final choice. Some of the contractors, for instance, can print labels for your pill bottles. Others have the ability to fill your bottles with pills, liquids, and other forms that you might manufacture. In some cases, hiring pharmaceutical contract manufacturing services from a third party could actually lower the operation costs. There are numerous companies that can offer the services that need .Pharmaceutical contract manufacturing can give the agility need to compete in today's global marketplace. Contract manufacturers in the drug industry can provide a relief valve from market pressures such as patent expiration and the demand for generics, discovering off-label uses for current formulas, pressure to speed up clinical trials, or keeping abreast on the development of new processes. Outsourcing to contract manufacturers in pharmaceuticals can answer some of the bigger challenges in today's global market:

1. Pharmaceutical contract suppliers around the world (particularly India and China) multiply the manufacturing capacity to match growing demand from emerging markets, especially Africa.

2. New technologies in drug delivery systems allow for reformulations of existing products - opening up pharmaceutical formulation possibilities to "mix and match" drugs and delivery devices that will extend product life cycles.

3. With new demand from new markets and new diseases comes new regulation, as governments step in to monitor and control the development and manufacturing process. Pharmaceutical contract manufacturers who specialize in clinical trials can alleviate that concern.

4. Even packaging benefits from technology, accurate and safer supply [1].

IMPORTANCE OF CONTRACT MANUFACTURE

There are many benefits as well as risks to contract manufacturing. Companies are finding many reasons why they should be outsourcing their production to other companies. However, production outside of the company does come with many risks attached. Companies must identify what their core competencies are first before deciding whether or not they should contract manufacture. A company's core competencies are what make them competitive in the market place. If a company allows another company to take control of them, it loses control over that advantage.

When making the decision on whether or not a company should contract manufacture, the company should weigh the benefits and risks associated with it. For small companies, contract manufacturing may not be a good business strategy. For large companies that are trying to grow and extend into new markets, contract manufacturing is likely to be a good choice [7].

BENEFITS

- **Cost Savings** – Companies save on their cost of capital because they do not have to pay for a facility and the equipment needed for production. They can also save on labor costs such as wages, training and benefits. Some companies may look to contract manufacture in low-cost countries, such as China, to benefit from the low cost of labor [2].
- **Mutual Benefit to Contract Site** – A contract between the manufacturer and the company it's producing for may last several years. The manufacturer will know that it will have a steady flow of business until then [2].
- **Advanced Skills** – Companies can take advantage of skills that they may not possess, but the contract manufacturer does. The contract manufacturer is likely to have relationships formed with raw material suppliers or methods of efficiency within their production.
- **Quality** – Contract Manufacturers are likely to have their own methods of quality control in place that helps them to detect counterfeit or damaged materials early on.
- **Focus** – Companies can focus on their core competencies better if they can hand off base production to an outside company.
- **Economies of Scale** – Contract Manufacturers have multiple customers that they produce

for. Because they are servicing multiple customers, they can offer reduced costs in acquiring raw materials by benefiting from economies of scale [3].

RISKS

- **Lack of Control** – As soon as a company signs the contract allowing another company to produce their product, they lose a significant amount of control over that product. They can only suggest strategies to the contract manufacturer; they cannot force them to implement them.
- **Relationships** - It is imperative that the company forms a good relationship with its contract manufacturer. The company must keep in mind that it is not the only customer to the manufacturer. They cannot force them to produce their product before a competitor's. Most companies mitigate this risk by working cohesively with the manufacturer and awarding good performance with more of their business.
- **Quality concerns** – When entering into a contract, companies must make sure that the manufacturer's standards are in line with their own. They should also evaluate the methods in which they test product to make sure the products being produced are of good quality. The company has to rely on the contract manufacturer for having good suppliers that also meet these standards.
- **Intellectual Property Loss** – When entering into a contract, a company is letting someone else in on their formulas or technologies. This is why it is very important that a company not give out any of its core competencies to contract manufacturers. It is very easy for an employee to download such information from a computer and steal it. The recent uptake in intellectual property loss has companies and government officials struggling to find the best method of security. Usually, it comes down to the integrity of the employees.
- **Outsourcing Risks** – Although outsourcing to low-cost countries has become very popular, it does bring along risks such as language barriers, cultural differences and long lead times. This could make the management of contract manufacturers more difficult, expensive and time-consuming.
- **Capacity Constraints** – If a company does not make up a large portion of the contract manufacturer's business, they may find that they are de-prioritized over other companies during high production periods. Thus, they may not be able to get the product they need when they need it.
- **Loss of Flexibility and Responsiveness** - Without direct control over the manufacturing facility, the company will lose some of its ability to respond to disruptions in the supply chain. It may also hurt their ability to respond to demand fluctuations, risking their customer service levels [7].

THE PROCESS OF CONTRACT MANUFACTURING

The process of contract manufacturing or outsourcing helps companies in many ways. Besides the attributes above, contract manufacturing also allows

companies to free up available resources so they can concentrate on other activities within the company. This is helpful if they have limited knowledge of the product they are trying to sell or the space to produce it. By using contract manufacturing, a company can contract with various companies to sell their products, while saving on costs.

Contract manufacturing does not just go for products. It can also be used when dealing with hiring outside contractors to perform services. One may have a client who needs specialized services to accomplish a certain task. Instead of losing the client, one simply go into contract with another contractor; in this case a subcontractor, and allow that person to fulfill that part of the contract.

Mostly contract manufacturing benefits companies who want to give their customers goods or services only they can provide, but using another company to provide or produce the goods, thereby lowering costs [8,9].

Find a drug contract manufacturer that provides a full-service menu

Avoid using a pharmaceutical contract manufacturer too small to handle more than one job, leaving with the headache of managing a long supply chain with small links. A pharmaceutical manufacturing company today should be able to handle a number of tasks, allowing concentrating on higher-end R&D.

Example: Located in Canada, Contract Pharmaceuticals Limited concentrates on customer-centric, full-service outsourcing, from manufacturing and packaging to testing services. NHK Laboratories, Inc. Manufactures a wider variety of products, in both the pharmaceutical and "nutraceutical" market - both dietary supplements and functional foods [6,9].

In order to gain the benefits of using contract manufacturing, it is best to take a strategic approach. Here are there areas one can focus on that will help better to prepare, manage contract manufacturing:

- Right mindset: In order to enter into a contract

REFERENCES

1. Anonymous 1. <http://www.businessdictionary.com/definition/contract-manufacturing.html>
2. Knowdell, Jenny. "The Benefits and Disadvantages of Contract Manufacturing." IQS Newsroom. Industrial Quick Search, Inc, 2011.
3. Cohen, Soshanah, and Joseph Roussel. Strategic Supply Chain Management: The Five Disciplines for Top Performance. United States: The McGraw-Hill Companies, Inc, 2005, 316.
4. Anonymous 2. <http://www.beginnersguide.com/manufacturing/contractmanufacturing/industries-that-use-contract-manufacturing.php>
5. Anonymous 3. http://www.ehow.com/info_8503681_advantages-disadvantages-contractmanufacturing.html
6. Anonymous 4. <http://www.beginnersguide.com/manufacturing/contract-manufacturing/Advantages and Disadvantages of Contract Manufacturing.php>
7. Anonymous 5. http://en.wikipedia.org/wiki/Contract_manufacturer
8. Anonymous 6. <http://www.beginnersguide.com/manufacturing/contract-manufacturing/the-process-of-contract-manufacturing.php>
9. Anonymous 7. <http://www.business.com/healthcare/pharmaceutical-contract-manufacturing/>
10. Anonymous 8. <http://www.pharmaceutical-drug-manufacturers.com/pharmaceutical-industry/future-prospects.html>

manufacturing deal, the company that wants to get involved must have the right mindset. They may want to look at the deal as if it is really an in-house arrangement. The basic precise here is the company wants to have a certain amount of control with the product. They want products that are known to sell and can be predicted as to what areas or territories the products will sell well at, so as to engage in affective marketing.

- Effective organization: To handle contract manufacturing, the business has to be developed and be effective in selling the product that he is contracted to sell. This is very important or the whole process will not work. There has to be stability in place along with the ability to keep grow and expand as the need arises [1].

FUTURE PROSPECTS

The dream of Indian pharmaceutical manufacturing companies for making their presence known globally and competing with the pharmaceutical companies from the developed countries like the United States, Europe, and Japan is now coming true. With new growth opportunities emerging in the pharma world, the pharmaceutical industry has shown great interest in India pharma sector due to its sustained economic growth, healthcare reforms and patent-related legislation [10].

CONCLUSION

The Indian pharmaceutical industry is also getting increasingly U.S. FDA compliant to harness the growth opportunities in areas of contract manufacturing and research. Indian companies such as Ranbaxy, Sun Pharma, and Dr. Reddy's are increasingly focusing on tapping the U.S. generic market. There are many multinational pharmaceutical companies who are looking forward to India as an attractive destination for Research & Development, contract manufacturing, clinical trials conduct and generic drug research. In 2005, the market value of Indian Pharmaceutical Industry was US\$ 45billion in 2005, and the generic sector is expected to grow to US\$ 100 billion in the next few years.