



CONTRACT MANUFACTURING IN PHARMA INDUSTRY

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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 having major share in contract manufacturing. The reason is that buying equipment for mass production of 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 making the decision on whether or not a company should contract manufacture, the company should consider the benefits and risks associated with it. Contract manufacturing is beneficial if the company gets involved with the right company, which is able to manufacture quality product.

Keywords: Contract manufacturing, Pharmaceutical Industry, Firm, Chemicals, Cost, out sourcing.

INTRODUCTION

Previously, the paradigm of the Pharmaceutical industry required companies to be vertically integrated, i.e., the company itself performed all the operations required of its business. Now investors are demanding continued high financial performance. As a result "outsourcing" has become a significant way of doing business. Outsourcing is the system of using a nonrelated for another on a contractual basis.^[1]

Contract manufacturing is a process that establishes a working agreement between two companies. As part of the agreement, one company custom produces parts or other materials on behalf of their client. In most cases, the manufacturer also handles the ordering and shipment processes for the client. As a result, the client does not have to maintain manufacturing facilities, purchase raw materials, or hire labor in order to produce the finished goods.^[2] It is a form of outsourcing.^[2]

Outsourcing has resulted in the development of a new paradigm offers companies new opportunities for improving their bottom lines through the conversion of fixed costs to variable costs. They accomplish this by reducing or eliminating in-house production

capabilities and replacing them with contract manufacturers. As a result, contract manufacturers that perform custom synthesis and produce intermediates, active pharmaceutical ingredients, and dosage forms are becoming increasingly important to the conduct of today's business. ^[1]

A Contract Manufacturing Organization (CMO) is an organization that serves the pharmaceutical industry and provides clients with comprehensive services from drug development through manufacture. ^[3]

Services offered by CMOs can be divided into two main activities: primary manufacturing and secondary manufacturing. Primary manufacturing involves the synthesis of the bulk active ingredients (drug substances) while secondary manufacturing refers to the formulation of bulk drug substances into the final drug products (pills, topical formulations, injectables) ^[3]

Types ^[1]

Contract manufacturing can be classified into two types, i.e. those who “supply” and those who “toll”. Regardless of type, all contract manufacturers have the common denominator of providing one or more services for a fee.

Supplier and Toller ^[1]

Contract manufacturer is one who supplies manufacturer's material for inventory. This supplier sells products from its inventory to one or more companies for their use or disposition. This type of contractor is sometimes known as an “original equipment manufacturer”. On the other hand, a “toll manufacture”, or “toller”, is a manufacturer who contracts to

- ñ Receive a raw material from another company.
- ñ Convert that material into another form, and
- ñ Return the converted material to the contracting company for its use or further disposition.

The basic difference between these two types of contractors is that one manufactures for its own inventory, while the other manufactures according to a custom order. To cloud this picture, either type of contractor may provide both functions.

Evolution of CMOs

The pharmaceutical market uses outsourcing services from providers in the form of contract research organizations (CROs) and contract manufacturing organizations (CMOs). In recent years, the concept of a comprehensive single-source provider from drug development through commercial manufacture has emerged. This concept has been implemented by providers known today as contract research and manufacturing services (CRAMS) or contract development and manufacturing organizations (CDMO).^[3]

CMOs are a response to the competitive international nature of the pharmaceutical market as well as the increasing demand for outsourced services.^[3]

The best-positioned service providers focus on a specific technology or dosage form and promote end-to-end continuity and efficiency for their outsourcing clients. With lower-cost international manufacturers capturing an increasing percentage of the contract manufacturing market, specialization may be an effective hedge against loss of market share.^[4]

Objectives and Relationship of Customer and CMO

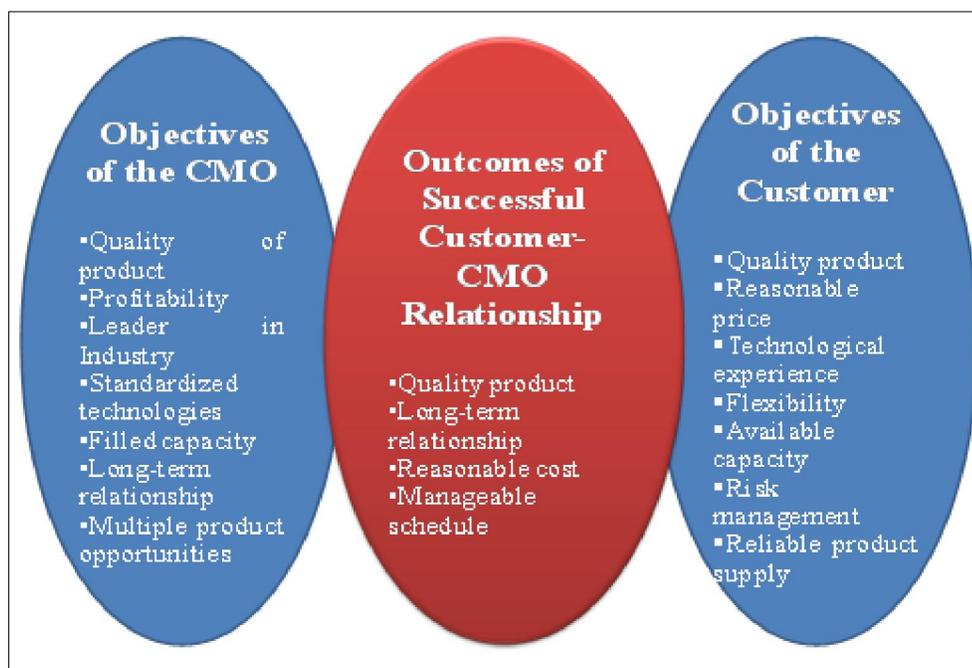


Figure 1: Relationship between the customer and the CMO^[5]

Business model^[2]

In a contract manufacturing business model, the hiring firm approaches the contract manufacturer with a design or formula. The contract manufacturer will quote the parts

based on processes, labor, tooling, and material costs. Typically a hiring firm will request quotes from multiple CMs. After the bidding process is complete, the hiring firm will select a source, and then, for the agreed-upon price, the CM acts as the hiring firm's factory, producing and shipping units of the design on behalf of the hiring firm.

Job production is, in essence, manufacturing on a contract basis, and thus it forms a subset of the larger field of contract manufacturing. But the latter field also includes, in addition to jobbing, a higher level of outsourcing in which a product-line-owning company entrusts its entire production to a contractor, rather than just outsourcing parts of it.

How to determine when a contract manufacturer is needed: ^[1]

The need for service of a contract manufacturer can occur at any time during the development phase and/or commercial manufacturer of a product's life cycle. Such situations occur when

- ñ Specialized manufacturing capabilities are required that are not available in-house.
- ñ Assistance is needed with product and/or process development.
- ñ The need to establish the market potential of a new product is required before investing in specialized capabilities.
- ñ Difficulty is encountered in breaking into the manufacturing schedule in a timely manner to produce small research, clinic, or commercial batches.
- ñ Production requirements cannot be accommodated when sales exceed capacity.

Capacity is needed for the production of new, growing product, yet a place for the manufacture of products that are at the end of their life cycle still needs to be provided

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 first identify their core competencies before deciding about 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 that advantage. ^[1]

For small companies, contract manufacturing may not be a good business strategy. For large companies that are trying to extend into new markets, contract manufacturing may be a good choice. ^[1]

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 producing company may last several years. The manufacturer will know that it will have a steady flow of business. ^[2]

Advanced Skills: Companies can take advantage of skills that they may not possess, but the contract manufacturer does. ^[6]

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. ^[6]

Focus: Companies can focus on their core competencies better if they can hand off base production to an outside company. ^[6]

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. The more units there are in one shipment, the less expensive the price per unit will be. ^[6]

Other benefits includes; the rapid use of technology, gain a global manufacturing presence, improved asset utilization, gain a window on a new technology, freedom to concentrate on core functions, faster time to market, access to market etc. ^[7]

Risks:

Lack of Control: When 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. ^[3]

Relationships: It is imperative that the company forms a good relationship with its contract manufacturer. The company must keep in mind that the manufacturer has other

customers. 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 additional business. [3]

Quality Concerns: When entering into a contract, companies must make sure that the manufacturer's standards are congruent with their own. They should evaluate the methods in which they test the products to make sure they are of good quality. The company has to rely on the contract manufacturer for having good suppliers that also meet these standards. [3]

Intellectual Property Loss: When entering into a contract, a company is divulging their formulas or technologies. This is why it is important that a company not give out any of its core competencies to contract manufacturers. [3]

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. [3]

This could make the management of contract manufacturers more difficult, expensive and time-consuming. [3]

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 obtain the product they need when they need it. [3]

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. [3]

Some other risk factors includes problem of monitoring supplier performance, problems of evaluating supplier performance, need for new management mind set, loss of critical skill, lack of shared vision, objectives, cultural differences, critical dependence on supplier. [7]

RFP Development [5]

The framework of the business relationship is initiated through the RFP (Request for Proposal). This becomes a vehicle that allows both the client and the CMO to establish a

dialogue, and to work from the same set of rules, requirements, schedules, and information. Its goal is to provide enough information and a framework of expectations to the potential CMO to receive a competitive bid with a detailed cost breakdown.

A properly formulated RFP will yield powerful results. It identifies potential suppliers through the definition of detailed initial requirements, establishes the project budget, and organizes project personnel.

The RFP details the tech-transfer steps, deliverables, and timelines, along with the expected production volumes. Investment of proper time is required to accurately define the details of this plan because it is critical to getting accurate bids having key functional areas aligned with the project. This will avoid misunderstandings later in the contract's lifetime.

The developed RFP is then presented to a short list of CMOs, followed by a series of discussions with each candidate to clarify the RFP and to share general philosophies and approaches – especially the quality philosophy. Concurrent with the RFP discussion is a GMP audit and a technical and reliability assessment. Also evaluate financial solvency by consulting knowledgeable credit agencies. Figure shows how organize an RFP

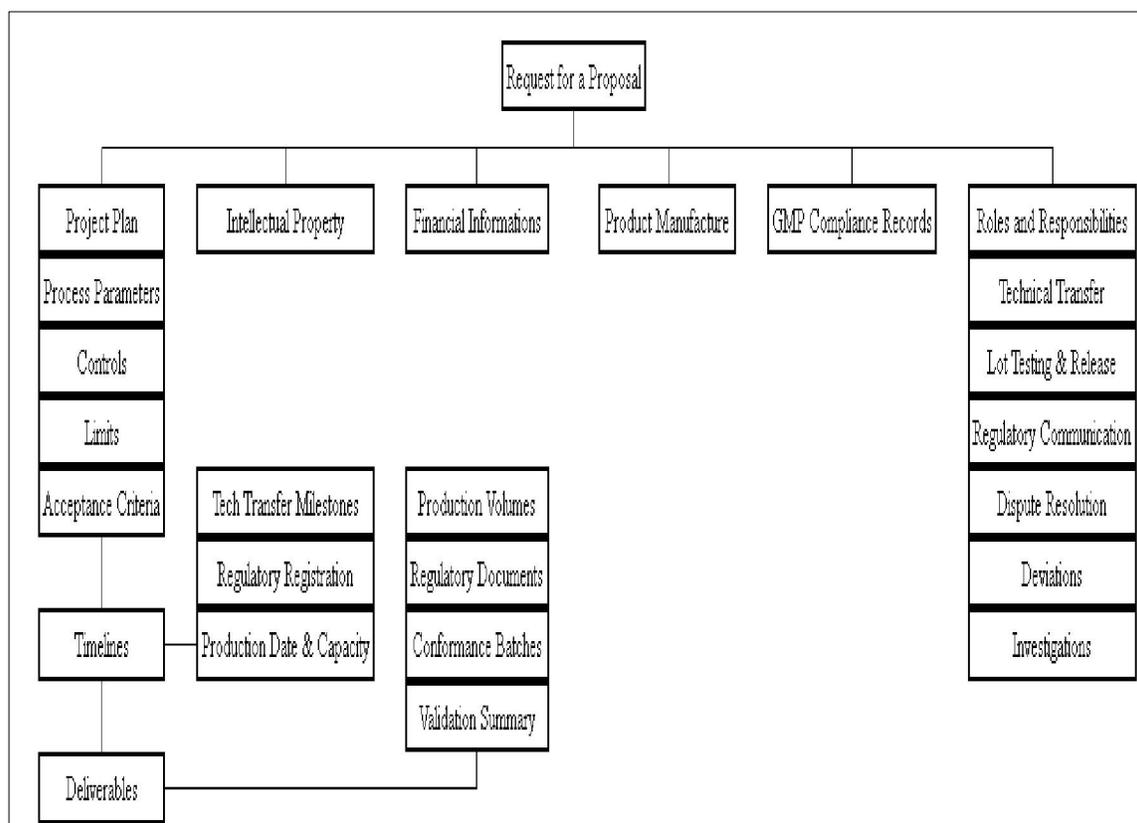


Figure 2: An RFP has seven main components and a fair number of subcomponents.^[5]

Centralized management ^[5]

Centralized management and a well-defined process are two elements that will enhance contract manufacturing. Managing through a central governance group ensures consistent and comprehensive practices, and also simplifies further refinement of the contracting process. In addition to a well-defined process, boilerplate agreements are tools that facilitate the dialogue between client and CMO and lead to agreements that meet the expectations and requirements that of both parties. In particular, the key manufacturing and quality roles and responsibilities will be carefully laid out in the supply and quality agreements.

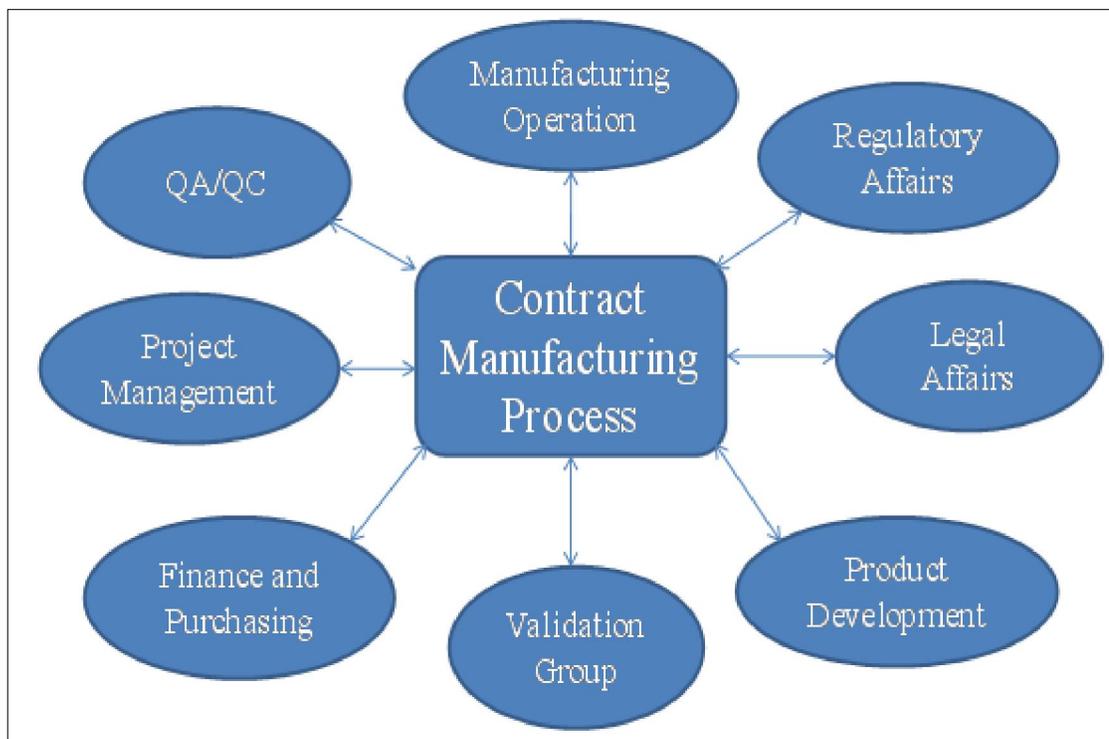


Figure 3: There are at least stakeholders who impact the contract manufacturing process ^[5]

In many companies, the business development group generally drives the contracting process. To be successful, however, the company's major stakeholders should be engaged (Figure-3). Participation into the initial process by these technical experts will result in a contract tailored for the transferred process and for the personnel responsible for executing and managing the agreement.

The Supply Agreements [5]

After the contractor is chosen, the next phase is to negotiate a supply agreement and a quality agreement. Each focuses on different sides of the business; the supply agreement focuses on the terms of the business. It will address minimum and maximum product quantities, payment terms, and contract duration. It will also define product-release criteria, product specifications, testing responsibilities for both companies' quality units.

The business Contract, or supply agreement (SA) defines the terms of the business relationship. The supply agreement details the costing, minimum and maximum delivery obligations, forecasting, and termination clauses (key Component of the supply agreement). It also provide for important procedural matters, such as technical transfer,

product testing and release, dispute resolution, site representation, regulatory inspections, process changes and improvements, and regulatory requirements. The SA also defines the need and responsibilities for important quality processes but does not define how they are performed.

Key Component of the Supply Agreement ^[5]

- Contract term
- Testing and specification for release
- Lot quantities, yield
- Price and payment terms
- Capital expenditures
- Minimum and maximum supply
- Lot rejection
- Termination review period
- Forecast and purchase orders and inspections
- Raw material purchase and vendor qualifications
- Technical transfer
- Process changes and continuous improvement
- Dispute resolution

Supply and Quality Agreements ^[3]

Once the CMO has been selected, the pharmaceutical company negotiates and concludes supply and quality agreements with the CMO. The supply agreement defines product quantities, product specifications, payment terms, and duration of the contract while the quality agreement ^[2] is a stand-alone document, which defines responsibilities between the client and the CMO and ensures that all operations are in compliance with the current good manufacturing practices (cGMPs). Generally, GMP regulations require from CMOs a strong system for standard operating procedure (SOPs), solid quality management systems, appropriately trained personnel, independent quality control (QC) or quality assurance (QA) units, and properly designed equipment and facilities.

The current GMP regulations for the manufacture of active pharmaceutical ingredients are defined in the guidance developed within the Expert Working Group (Q7A) of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

Additionally, according to the current regulations in the European Union, products manufactured in Europe must be certified by a Qualified Person (QP) prior to use in the clinic or release on the market.

The contract manufacturing opportunity ^[8]

Having realized that manufacturing cost reduction is a key to participating in the critical generics space; global pharma firms have been exploring means to achieve this end. Key initiatives that can be explored to reduce manufacturing cost to 15% can include innovation, process redesign and consolidation; however the option with the best cost-quality advantage at lower capital investments is contract manufacturing. ^[8]

India's contract manufacturing opportunity ^[8]

India has the largest number of USFDA approved pharma plants worldwide, after the US - a total of 75 plants. This is three times more than the number of plants in China which have FDA approval. This not only reflects the quality of the Indian pharma industry but also the depth of expertise that exists industry-wide. More USFDA-standard trained personnel area available in India than in China - thus making it easier for newer entrants to get certification. However for international firms looking at India there is a bugbear-most of the large Indian firms are key competitors in the generics market - thus there is exposure of process, systems, quality standards which makes global firms uneasy. Hence the field is open for the stand-alone contract manufacturing company. With the global contract manufacturing opportunity expected to rise to 140 Bn US \$ by 2009, and Indian contract manufacturing market size expected to be at 1.7 Bn US\$ by 2009, the standalone contract manufacturing business is poised to explode in India. Firms that have a head-start, who have experience and systems to handle rigid quality requirements of global firms can expect to participate strongly in the boom. The other side of the coin however could very well be start-up contract manufacturing firms - armed with global contracts and

funds from venture capital - they could very well form the next global beaters after IT in India. ^[8]

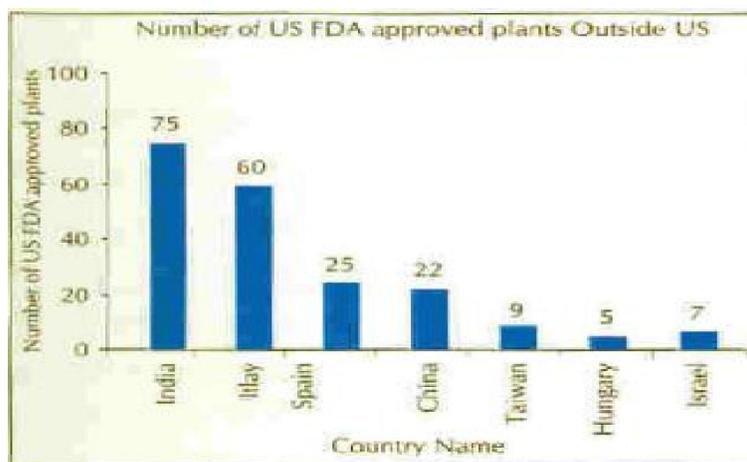


Figure 4: Number of US FDA approved plants outside US ^[8]

Contract manufacturing is a strong segment of the domestic market. Indian firms have several advantages over their Western rivals. The expertise gained in manufacturing generics through reverse engineering has helped some companies streamline the process for getting manufacturing up and running. Costs are very competitive; indeed, they are only two-fifths of those involved in setting up and running a new manufacturing facility in the West. ^[8]

They can operate on significantly lower margins, given their low development and labour costs. Currently their key area of strength in outsourcing is the manufacture of APIs. Some Indian pharma companies could probably benefit significantly by moving towards specialty APIs in the future.

The Indian contract manufacturing segment was worth around US\$605 million in 2008 and is expected to reach around US\$916 million in 2010. The US FDA has already approved over 100 manufacturing sites – more than in any country except the US (Figure 5). ^[9]

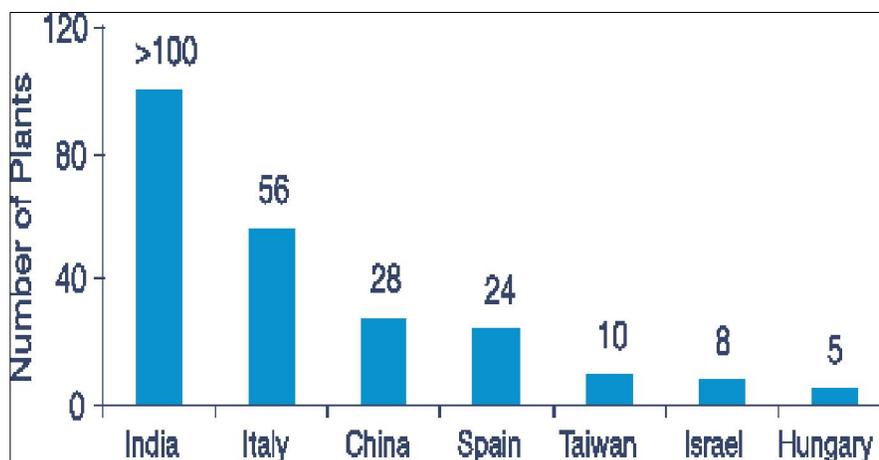


Figure 5: India has more US FDA-approved manufacturing plants than any country except the US. ^[9]

(Source: Crisil Research, Bulk drug exports to scale up in the regulated markets (December 2008) for India; ICICI Securities, Indian Pharma Sector:

Sector Update (December 2008) for Italy, China, Spain, Taiwan, Israel and Hungary.)

Among six offices that the US FDA has overseas, two are located in India, in Delhi and Mumbai. ^[9]

All domestic producers are also obliged to comply with India's Good Manufacturing Practices, under Schedule M of the Drugs and Cosmetics Act, 1940. Indian manufacturers are currently facing some scrutiny around quality issues. In 2009, the US FDA took action against a few Indian companies after conducting a series of inspections and issuing warning letters against these drug makers. While such sanctions clearly pose significant challenges, some analysts see an opportunity as well. Indian companies are aggressively improving their manufacturing standards in response, and are therefore likely to be better positioned to take advantage of the upsurge in generics production expected as patents expire over the next five years. ^[9]

Some Indian manufacturers are also now incorporating Lean Manufacturing and Six Sigma principles to help them boost operational efficiency and further improve quality, while facilitating compliance. ^[9]

The process of contract manufacturing ^[10]

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 goes into contract with another contractor; in this case a subcontractor, and allows 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.

Future prospects ^[10]

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.

It is critical that both the contract manufacturer and the sponsor put controls in place and the sponsor has a mechanism to monitor the effectiveness of these measures.^[11] Robust quality systems have been proven to reduce compliance issues and more rigorous supervision has deterred non-compliance. It is important to delineate the responsibilities of the sponsor or applicant holder and the contract manufacturer. The expectations of the US Food and Drug Administration (FDA) are outlined in their Guidance for Industry Cooperative Manufacturing

Arrangements for Licensed Biologics.

The applicant holder is responsible for; ^[11]

- Ensuring the identity, purity, strength, quality, potency, safety and efficacy of the product.

- Ensuring that the manufacture of the product complies with the provisions of the application and the applicable regulations including, but not limited to, 21 Code of Federal Regulations (21CFR) parts 210, 211, 600-680 and 820;
- Using adverse event, and product complaint reporting systems;
- Developing and validating the production process; and
- Reporting changes to the production process.

The contract facility engaged in the manufacture of a drug or device is responsible for; ^[11]

- Compliance with applicable provisions of the Food, Drug, and Cosmetic (FD&C) Act (21 USC 301) and applicable regulations, for example current Good Manufacturing Practices (cGMPs); and
- Registering with the FDA in accordance with registration and listing provisions in 21 CFR parts 207, 607 or 807.

Quality system that can result in potential compliance issues with contract manufacturers ^[11]

The contract manufacturer may sometimes implement changes that could affect the quality, safety or efficacy of the product without proper regulatory approval. The consequences of this have significant regulatory impact; the most serious being that the drug may be deemed as misbranded and adulterated as per the Food and Drug Act. The sponsor must ensure that the change control process builds in an explicit system that prevents implementation of any change until appropriate internal units have authorized it. Any change must be justified and within the scope of the approved application. The FDA's approval is required for changes that are categorized as 'major' and require prior approval. Some changes may be implemented within 30 days of notification to the FDA while the most minor changes can be made effective immediately. The FDA's guidelines on Scale-Up and Post-Approval Changes (SUPAC) unambiguously outline requirements for both solid dosages, and semi solids. There must be sufficient checks and balances within the system to prevent premature implementation of changes. Common changes include: improvement of test methods or changes to manufacturing equipment, excipient manufacturer, testing facility or starting material. The contract manufacturer should also

share all significant proposed changes to production and facilities with the applicant. The applicant holder is responsible for reporting these. Corrective and Preventive Action (CAPA) procedures can be overlooked quite easily. CAPAs are usually specified as solutions to problems revealed during investigations into manufacturing or testing errors found during an inspection. The CAPAs are meant to correct the problem and prevent it from recurring. Due dates are often missed, and root cause analysis may not have adequately addressed the problem. This means that the same errors and deviations can recur. The sponsor must be directly involved in ensuring that all CAPAs have been addressed fully, adequately and in a timely manner. Some organizations use commercially available software to aid in the follow up process. However, the use of this software is dependent upon the people using it, and the commitment made by a firm.^[11]

An Annual Product Review (APR) is a compilation of the quality attributes of each drug manufactured by a manufacturing facility. The Code of Federal Regulations (CFR)^[10] requires a review of each batch, whether approved or rejected and, where applicable, records associated with the batch. A review of complaints, recalls, returned or salvaged products and investigations are also part of the APR. If it is thoroughly done then product trends become visible and allow the manufacturer to draw conclusions. An APR is an excellent tool to ensure the product and process is still within a state of control. The sponsor must set-up processes to clarify the roles and responsibilities within an inter-company document such as a Quality Agreement. The sponsor is ultimately responsible for reviewing the APR to ensure that the product is still being manufactured and tested as per the application, and the process remains in a validated state. Customer complaints are an area of concern because of their seriousness and time sensitivity. Timely cooperation of the contract manufacturer is vital. The complaint investigation may necessitate testing and batch record review, which can be time-consuming; however these activities cannot be avoided. A monthly review of all complaints must be done to examine if there are any trends with the product or with a specific lot. Complaints illustrate the product performance in the marketplace and must be taken seriously by the sponsor and contract manufacturer to identify manufacturing, testing or clinical issues. For example, many complaints may point to a flaw in manufacturing or equipment. Problems like these are deep rooted, and deserve attention, as well as resources committed to their resolution.^[11]

The applicant or sponsor should be fully informed of; ^[11]

- All deviations, complaints and adverse events;
- The results of all tests and investigations regarding or possibly impacting the product; and
- Procedures that the contract manufacturer uses for assessing the compliance of their facility.

Executive Summary ^[12]

Pharmaceutical manufacturers have increasingly turned to the resources and experience of external companies such as contract manufacturing organizations (CMOs) to manufacture finished products in their portfolios and new drugs for clinical trials.

In May 2012 Pharma IQ conducted a survey with 100+ professionals from various functions in the pharmaceutical industry to establish the trends that enhance the ability for pharmaceutical and biotech companies to pick the right outsourcing partner.

Key Findings ^[12]

- 77% of companies currently use a contract manufacturing organization
- 31. % of survey participants cited access to technology and equipment as their key driver for contracting
- Managing operating costs is of paramount concern: 44% of respondent said operating costs will have the biggest impact on their contract manufacturing strategy in 2014
- 63% cited product quality as the most critical success factor for pharmaceutical contract manufacturing
- The majority of respondents said the greatest challenge they faced when working with contract manufacturers was maintaining quality. 18% of companies said their relationships with contract manufactures did not meet expectations.

Key Drivers for Contracting ^[12]

With the recent economic recession, which continues to severely impact drug makers across the world, pharmaceutical firms have increasingly looked for new ways to minimize their costs. As a result, Pharma IQ forecasts that the global market for pharmaceutical contract manufacturing will continue to witness robust growth. This is supported by Global Industry Analysts “Pharmaceutical Contract Manufacturing Report”

published in January 2011, which predicted that the global pharmaceutical contract manufacturing market will reach \$40.7 billion by 2015. The report which analyzed some of the drivers behind this expected growth such as technology and regulation said: "Pharmaceutical manufacturing entails sophisticated technology and strict regulatory compliance. Outsourcing such activities to CMOs enables a Pharma company to expedite its R&D, and thus realize the potential revenues." For most companies, there is normally more than one factor behind the decision to outsource some or part of its global manufacturing.

However, cost-saving potential and access to resources, such as technology or equipment remain among the main attractions of external production.

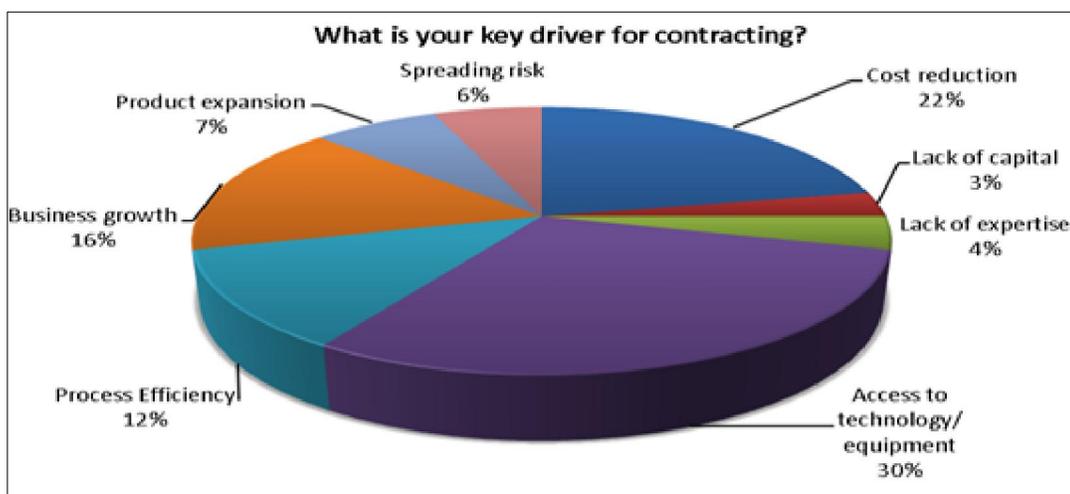


Figure 6: Key Drivers for Contracting ^[12]

The majority of survey participants, 30%, cited access to technology and equipment as their key driver for contracting out their manufacturing operations.

This was closely followed by cost reduction at 22%. The remaining respondents, cited business growth (16%), process efficiency (12%), product expansion (7%), spreading the risk (6%), lack of expertise (4%) and lack of capital (3%) respectively.

Contract Manufacturing Alliances ^[12]

Finding a suitable contract manufacturing organization (CMO) that meets your business needs, can be an expensive and time-consuming process. With so many CMOs to choose from, pharmaceutical companies can spend a great deal of their time in the decision making process to find the right partner that will provide the services they require with minimal risk and maximum efficiency.

Challenges for the Industry ^[12]

One of the challenges for pharmaceutical companies and contract manufacturers is to align their own internal company in terms of culture as well as of operations.

The survey respondents were asked what challenges were having the greatest impact when working with contract manufacturers. For 34% the greatest challenge was maintaining quality, for 21% maintaining regulatory control and compliance and for 15% of respondents

maintaining cost control. The remaining respondents cited production planning (13%), production volumes (8%), establishing contracts (4%), maintaining control over IP (3%) and process re-engineering (2%) respectively.

Pharmaceuticals companies and contract manufacturers must have a collaborative approach to these challenges, written quality agreements in place and mature quality systems in place to prevent and detect problems. Product quality was the most critical success factor for over 60% of the survey respondents.

The remaining participants said delivery schedule 12%, cost effectiveness for 11%, CM/customer relationship 8% and experience at 6%.

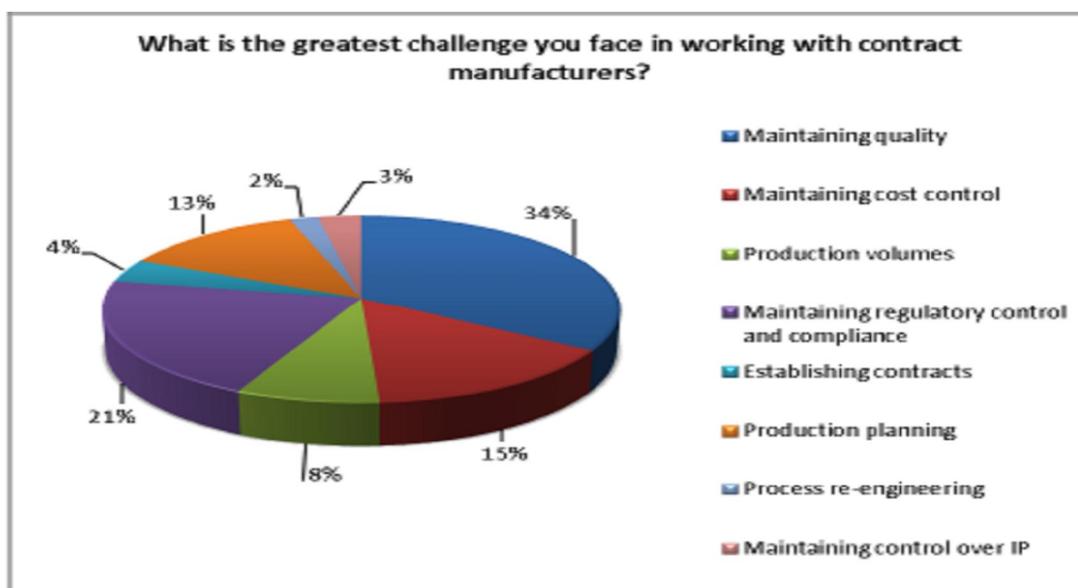


Figure 7: Challenges for the Industry ^[12]

HOW TO DETERMINE WHEN A CONTRACT MANUFACTURER IS NEEDED

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- Production requirements cannot be accommodated when sales exceed capacity.
- Capacity is needed for the production of new, growing product, yet a place for the manufacture of products that are at the end of their life cycle still needs to be provided.

CONCLUSION

With the skillful management and control, contract manufactures can be used to take a product from the "test tube miracle" stage through the stage of being a "production masterpiece." Virtual companies have learned to do these tasks well, and have successfully linked multiple contract manufactures together to form the horizontally integrated of the future.

There are many changes occurring in the pharmaceutical industry. Also patent rules are change, so many companies now concentrating on R & D work. To accommodate this changing terminology, the core business of many companies will require capabilities that they do not presently have to acquire this manufacturing capacity. They require huge funds available with them, so instead of investing their own limited capital in manufacturing facilities, they prefer outsourcing. So in today's economy outsourcing is preferable.

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 conclusion, a unique opportunity is emerging for stand-alone contract manufacturing pharma firms, which will much like the BPO opportunity, be driven by knowledge than money power. Companies that can institutionalize processes, systems and experience will gain in this race for the next big boom in Indian industry.

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