An Investigation Exploring the Advantages and Disadvantages of Outsourcing the Development of New Products in the Indian Pharmaceutical Industry

Horacio Soriano-Meier  
Northampton Business School  
The University of Northampton, Northampton, NN2 7AL, UK

Jose Arturo Garza-Reyes  
School of Technology  
The University of Derby, Derby, DE22 3AW, UK

Jasdev Singh Lal  
Northampton Business School  
The University of Northampton, Northampton, NN2 7AL, UK

Luis Rocha-Lona  
National Polytechnic Institute of Mexico  
Business School, Mexico City, 03100, Mexico

Abstract
A common practice in the Indian pharmaceutical industry is to continually assess the feasibility of manufacturing their products in-house or allowing contract manufacturers to produce those products on their behalf. In this context, the pharmaceutical industry in India is one of the most highly organised business sectors. The purpose of this study is to investigate which key factors have an impact on the decision-making process when outsourcing the development of new products in pharmaceutical companies in India. To do this, the study followed a qualitative research approach. In particular, semi-structured interviews were conducted among four top manufacturing managers and four top outsourcing managers, involved in the outsourcing decision-making process, in order to uncover the key elements that drive the outsourcing of new product development (NPD). The present case study not only elicited the NPD key outsourcing drivers, but it also provides the conceptualisation of those drivers. Uncovering the outsourcing drivers in this sector will help top managers of this industry to improve and streamline the NPD outsourcing decision-making process.

Keywords  
Contract manufacturers (CMs), contract providers (CPs), Indian pharmaceutical industry, new product development, outsourcing

1. Introduction
Outsourcing is a common practice among both private and public organisations and is a major element of the business strategy [1]. The process of outsourcing can be looked upon as a strategic move among businesses. This process would try and decrease the overall cost of maintaining or increasing product quality. It may also allow firms to focus their concentration towards core activities of the business. During the last three decades, researchers have supported this phenomenon as one of the most effective ways for cutting down costs. However, the overall impact of this approach remains an unexplained conundrum [2].

On the other hand, the process of new product development (NPD) is said to be a knowledge-intensive activity, as it is very much dependant on different activities involved in the process. It also relies upon the capability to handle the related uncertainties throughout the entire activity. Therefore, some considerations with regards to knowledge acquisition and indecision need to be addressed [3]. According to Ford et al. [4] “cost reduction has
been the dominant motive for outsourcing”. Thus outsourcing NPD can be considered as a mean to reduce the high cost involved in the process of developing and manufacturing new products [5].

The pharmaceutical sector in India has travelled an extensive distance, from being fictional before the 1970s to a well-known contributor towards the Indian healthcare industry. In the field of complex drug manufacturing, India has proved its competency by creating almost every complex drug indigenously. The high quality of Indian drug manufacturing facilities has driven the approval of regulatory authorities from countries such as USA and the UK to support many production facilities within India [6]. Globalisation has lead to a situation of instability; as a result, NPD has rapidly declined due to the high cost involved in developing them. In particular, the Indian pharmaceutical industry has adopted outsourcing as a strategic method to cut down the high cost involved in NPD [7].

The main objective of this research is to determine why more pharmaceutical firms are opting for outsourcing the development of new products. In addition, this research also investigates the reasons behind their decision to outsource, what goes into the decision-making process and what the factors that influence and drive such decision are. Finally, this research also develops an understanding of the decision-making process when outsourcing NPDs. As the process of outsourcing NPDs is a fairly new process within the Indian pharmaceutical sector, it needs to be adapted to the current practices and strategic concepts that create a benchmark in the global outsourcing world [6].

2. Outsourcing background

According to Gnuschke et al. [8] “outsourcing occurs when an organisation transfers some of its tasks to an outside supplier and offshore outsourcing occurs when these tasks are transferred to other countries”. Then after, it refers to assigning an individual or a specific project, task or area of responsibility to a source, which is not a direct part of the organisation. The third-party unit can be a contractor, development house or a specialized firm. “Outsourcing is the process of establishing and managing a contractual relationship with an external supplier for the provision of capacity that has previously been provided in-house” [9].

Perunović and Pedersen [10] have designed a framework to facilitate the understanding of the outsourcing process. In their framework, Perunović and Pedersen [10] have grouped the various stages that the outsourcing process consists of. The framework (see Figure 1) consists of a sequence of stages such as preparation, vendor selection, transition, managing relationship and reconsideration. Their contention is to view these stages as questions related to the complex process of outsourcing. This framework tries to explain the outsourcing process in the form of process life cycle [10].

![Figure 1: Framework for the process of outsourcing (Perunović and Pedersen [10])]
Outsourcing is an active process that correlates with the strategic changes of an organisation which continually adapts its decision-making process to improve performance. Momme and Hvolby [9] proposed a conceptual framework of the outsourcing process, see Figure 2. This framework consists of three phases, with two generic steps in each of them. Momme and Hvolby’s [9] framework aims to link the tactical and operational considerations of the outsourcing process to the strategic business planning. It demonstrates how the entire outsourcing process is linked to its sequential steps from start to finish and from a buyer supplier perspective, which means that one generic step provides input to the next one and so forth [9].

![Outsourcing framework adapted (Momme and Hvolby [9])](image)

An ideal outsourcing process is one where the internal client does not notice that outsourcing has taken place, but realises that cost and services have improved [11].

2.1 Complimentary strategic initiative
There are many strategies involved when it comes to delivering a competitive sustainable advantage with respect to outsourcing. Thompson et al. [12] indicate that “there are many routes to competitive advantage; however they all involve giving buyers (i.e. customers) what they perceive as superior value”. As for many organisations the decision of outsourcing is looked upon as a strategic initiative, thus an option must be selected by the organisation to pursue any one of the following strategies shown in Table 1.

<table>
<thead>
<tr>
<th>Strategies</th>
<th>Overview</th>
</tr>
</thead>
<tbody>
<tr>
<td>A low-cost provider strategy</td>
<td>Gaining a cost-based competitive advantage over rivals. An organisation must be more skilled than rivals in controlling cost drivers and eliminating cost-producing activities</td>
</tr>
<tr>
<td>A broad differentiation strategy</td>
<td>Strategy seeks to produce a competitive edge by incorporating unique attributes and features into the company’s products</td>
</tr>
<tr>
<td>A best-cost provider strategy</td>
<td>Create competitive advantage by giving buyers more value for money</td>
</tr>
<tr>
<td>A focused (or market niche) strategy based on lower cost</td>
<td>Deliver competitive advantage by achieving lower costs in this niche market</td>
</tr>
<tr>
<td>A focused (or market niche) strategy based on differentiation</td>
<td>Deliver competitive advantage by the ability to offer niche buyers something unique</td>
</tr>
</tbody>
</table>
After selecting and implementing the most effective strategy, it is important to decide on the strategic action required to be taken. This should match the firm’s choice of basic strategy, for example, strategic alliances and collaborative partnerships (i.e. mergers and acquisitions, integrate backwards and forwards) and outsource selected value chain activities (i.e. initiating offensive strategic moves or defensive strategic moves) [12].

2.2 Outsourcing decisions
The ability to make successful outsourcing decisions depends on various factors and considerations. There are two forms of outsourcing decisions that form the basis for long-term or short-term benefits to the firm. These, according to Phelps and Fleischer [13] are as follow:

- **Strategic outsourcing**
  It is based upon a strategic decision of the firm, the firm decides if it wants to make or buy a type of product. If the decision is to buy the product or service then it closes the facilities that currently produce those products. This shows the importance of the strategic decision of closing down its production facilities, left with no other option than trusting an external supplier for its production.

- **Tactical outsourcing**
  It is based on a tactical decision of the firm, the firm decides if it wants to make or buy a specific part to manufacture the product in-house. It is nearly possible that a series of tactical decisions may lead to a strategic outsourcing decision. A tactical decision is looked upon as an experimental stage of trial and errors in certain particular cases. The buyer-supplier relationship formed during a tactical decision is completely different to the one formed during the strategic decision-making process. A tactical outsourcing decision may always be perceived as short term association.

3. Outsourcing and NPD
According to Krishnan and Loch [14] “NPD can be defined as the set of activities that start with responding to a market opportunity and ends with the delivery of a differentiated product or service”. The newness in relation to product development can be defined based on the low/high degree of technological innovation with respect to low/high degree of market newness. It is very important to determine to whom the product would be new so as to determine the extent of newness of the product. Further, Garcia and Calantone [15] explained that there are five different classes for whom the product can be new, such as new to the world, new to a scientific community, new to customers, new to the market and new to a firm. Thus “newness is categorized based on the size of the population to whom the product is new” [5].

As the NPD process is differentiated in two parts, namely: idea generation and market analysis, in this paper, outsourcing of NPD can be referred to as the development of a new product, such as a good or service, by externally purchasing the product design or detail engineering using a suitable outsourcing strategy from the outsourcing firm [5, 14].

Arguably new products constitute the lifeblood of the pharmaceutical and biotech industries. Nearly all companies in this sector concentrate on developing new products, escalating revenues and reducing the cost of doing so. This in turn generates a positive return on assets enabling an upsurge in the company’s stock price and ensuring stockholders’ satisfaction. However, every successful business strategy requires specific team-based projects delving on improving the existing processes. One of the many strategies that pharmaceutical and biotech companies adopt currently is to outsource numerous traditional “non-core” elements of their business [5]. This implies defining the “core” elements of the business. Outsourcing has become the answer to the companies’ complications in meeting the aforesaid goals.

4. Outsourcing in the pharmaceutical industry
Dubourg [16] has aptly pointed out the consequences, particularly for pharmaceutical organisations, of not outsourcing key business processes. Dubourg [16] elucidates that the running of all company operations under one roof may lower/damage the company’s performance thereby negatively impacting its balance sheet. This mode of operation wherein companies engage their entire workforce in all stages of product manufacture, ranging from the manufacture of their own active and non-active chemicals compounds (i.e. raw materials) to packing of the finished product, is referred to as vertical integration.

The global contract manufacturing market for the pharmaceutical sector is forecasted to increase at a rate of 8% per year and to exceed $26 billion by 2011 [17]. There has been an impact that is unique, innovative, and state-of-the-art processes and production technologies, which have been offered by contract manufacturing firms in
scripting the success story of the pharmaceutical industry [18]. The manufacturers need to bear in mind the need for huge investments in procuring modern technologies and resorting to new practices if they do not favour outsourcing. Although cost is an important driver [19, 20, 21] it is not the only one. In addition to cost and capacity issues, the academic literature also mentions other important factors (i.e. key drivers) that influence organisations to outsource. These include fast cycle development, expertise, technology and performance.

According to Jiang and Qureshi [19] the following are the reasons why pharmaceutical companies must resort to outsourcing.

- **Cost savings and cost restructuring**
  Outsourcing transfers the balance of fixed costs to variable costs. Additionally, the overall costs can be lowered by selecting low cost economies, such as China and India as offshore locations for outsourcing [19, 22].

- **Reduced time for product marketing**
  Outsourcing enables to reduce the total time allotted to a project for developing or manufacturing drug substances. This in turn shortens the time to market the product. This is translated to quicker income and long duration of patent life. Consequently, the company develops the capacity to introduce new products into the market.

- **Flexibility**
  Outsourcing renders flexibility to the outsourcing firm. The outsourcing firm can make strategies to lower company expenditure by reducing fixed costs and modifying capacities.

- **(New) Technologies**
  With outsourcing, a company can gain access to (new) technology. Owning complex, new technology may not be feasible. On the other hand, outsourcing provides access to this technology on a need basis thereby imparting organisational flexibility.

- **Skills, knowledge and operational expertise**
  Outsourcing gives access to external intellectual property rights, a larger talent pool and a sustainable source of skills that would be too difficult to gain or time consuming to develop in-house.

- **Contract**
  Outsourcing services will be contractual and legally binding in nature, accompanied with financial penalties and legal regress.

5. **Outsourcing in India**

According to a survey conducted by Corporate Catalyst India [17], India is placed at number one spot for developing drugs that are approved by the US Food and Drug Administration (FDA). The Indian government’s decision to revive regulations on patents of medicine has created global opportunities for India. According to a report produced by Ernst & Young [23], eighty percent out of the 38 big and medium size pharmaceutical firms across the globe chose India as their destination to outsource new product development. In this context, “India is poised to become the strategic partner of choice in contract manufacturing” [23].

The strategies of using outsource partners to develop new products and concentrating on the core competencies of the firm is the future that lies ahead of the pharmaceutical Indian organisations [24]. As many private organisations are accepting the challenge to manage relationship with their manufacturers so as to generate value, there is a need to resolve matters relating to proprietary knowledge and confidentiality for a better outsourcing future in India. Outsourcing, if identified correctly, can prove to be a solution to the pharmaceutical companies during this phase of downturn [25].

6. **Research Method**

This study is based on observable reality wherein data is not under the influence of the subject or researcher. As this study was based on the analysis of top management decision-making input, semi-structured interviews via e-mail/post and telephone were selected as the data collection method that best fitted this study. In this research, an inductive approach was chosen to answer all the research questions. Inductive reasoning moves from specific observations to broader generalisations [26]. This study gathered data from eight different sources classified in two particular contexts, namely: contract providers (CPs) and contract manufacturers (CMs).

It is beyond doubt that the data collection process must be carefully structured and executed. Data collection is a laborious process, particularly in this research as the providers (i.e. top managers) are quite busy subjects. As top managers are difficult to be approached, the researchers agreed with them to prepare a qualitative questionnaire with the interview questions to be sent by post/e-mail to these managers. This approach was the
best and quickest way to get them focused when providing their answers. Then after, the researchers requested related input in order to further clarify their responses, as a way to facilitate the telephonic interview due to inherent practicalities. The current research involved mono method, which is based on qualitative data. This qualitative approach defines what is significant and what is not, particularly when there is very little data available on the selected topic and when the variables are unknown or when inadequate research has been done about the study [26, 27].

As there is not much written in this topic, the researchers decided to take the views of people who are directly involved or are part of the NPD decision-making process as they are the key players when outsourcing NPDs. Thus a decision to interview operations/business development heads led to the selection of this qualitative case study approach. As the qualitative case study data needed to be obtained through semi-structured interviews, pilot interviews with colleagues and academics were conducted to prepare and refine the interview questionnaire in the form of an MS Word format. The selection of this qualitative approach provided the researchers the flexibility to interview participants from various organisations thus leading to a broader conclusion.

As agreed by the interview respondents, questionnaires were e-mailed to them for their perusal and participation. Two different sets of questionnaires were e-mailed to eight different pharmaceutical companies located in India, four to contract manufacturers and four to contract providers. The entire process of interviewing the participants and validating the interview questionnaire took about 11 weeks. Coomber [28] justified that e-mail interviews are considered advantageous, “due to asynchronous communication of place, is the extended access to participants”. In addition, Bampton and Cowton [29] said “e-mail interviewing provides a limited register for communication.”

Keeping in mind the limitations of e-mail interviews, the researchers used a triangulation approach. Sachdeva [27] explained that “triangulation involves using multiple data sources in an investigation to produce understanding”. Sachdeva [27] further added that multiple methods may create a better understanding for particular phenomenon. In order to follow and clarify the responses obtained via e-mails, the researchers contacted the respondents through telephone, thus making the data reliable. The data from semi-structured interview was saved in MS Word format [26].

All ethical issues were considered in the study. The study selected and approached the participants by their own interest by contacting them personally and letting them know about the research topic in advance before conducting the interview. The study caused no harm to a participant nor intruded his/her privacy. The confidentiality of the data provided by the participants was ascertained. Access to company information was gathered in a legitimate manner without causing misuse. Data collection was complete and accurate. There was no employment of personal data.

The study dealt with qualitative data, which in turn can threaten its reliability owing to use of perceptions and interpretations. The above threat was eliminated by conducting eight interviews via e-mail, which provided the participants a comfort to answer the questions according to their conveniences. The most important aspects of data analysis in a qualitative research study are the corroborations and validation of data input, data recording and the results. It is essential to validate the qualitative data throughout the analysis, collection and writing-up process [29]. To validate the research, e-mail interviews were followed up by telephonic conversation to clarify the responses of the participants. A detailed transcript of the interviews conducted were prepared and stored in a Word format for further references and data analysis.

The final data was analysed using an interpretive technique called coding. In coding, a response is analysed and significant segments are demarcated with a code. The code consisted of a word or short phrase indicating a relation between segments and the research question. The data segments were compared through a node tree hierarchy thereby leading to a better understanding of the codes. Creation of node trees led to identification of codes. This can be done manually as well as by using a software program [26, 27]. In this research, the qualitative analysis was done using the QSR NVivo9 software, which is specially designed to analyse qualitative data and reduces the need for traditional filling methods. The software involves a system where all the transcripts can be analysed in one single go. Since the interview consisted of the same set of questions, it was easy to analyse them using NVivo9’s ‘auto code’ tool. This tool provided the auto code with all the answers to each question by putting each and every answer of different respondents together. As a result, all the data could be preserved in digital form, allowing it to be copied and safe from accidental loss or damage.

7. Results and Discussion
The main purpose of this study was to determine why pharmaceutical companies in India are opting to outsource new product development (NPD). In doing so, the study tried to understand the decision-making factors to outsource NPD.

7.1 The drive to outsource
The main reasons to outsource in the pharmaceutical industry, as suggested by both CPs and CMs, were found to be (1) cost reduction, (2) flexibility, (3) technology transfer, (4) fast product development and (5) expertise acquisition. To be able to focus on core competences and executing an expansion plan are the two benefits that created a difference in opinion, as stated by CPs and CMs. Focusing on core competences is said to be one of the important advantages. Although cost is an important driver, it is not the only driver [21, 22, 23].

The outsourcing expectations are directly linked to the reasons for outsourcing. The findings indicate that the CMs know exactly what the needs of the CPs are and thus they try to fulfil all their objectives. Hence, it is not about manufacturing NPD at low cost, but there are other aspects attached to it as well [21]. The making or buying criteria according to the respondents were either a strategic development or future plan of expansion. Both the CPs and CMs were reluctant to give an in depth idea of what goes in to making or buying criteria.

7.2 Outsourcing - strategic initiative
There is a link between the outsourcing strategy and decision-making. Depending upon the organisations strategy the decision to make or buy a new product is put forth. Phelps and Fleischer [13] advocated two types of outsourcing decisions, strategic and tactical. The participants’ feedback suggested that they understand the relation between the strategy and decision-making. But no one could explain or justify the relation between them.

According to both CPs and CMs, outsourcing of NPD can definitely create sustainable competitive edge over in-house production. Though there were mixed opinions about whether it may create a competitive advantage over competitors. The pharmaceutical companies are looking for assistance with technologies and product development [20]. Kremic et al. [1] mentioned that firms should only produce those products in-house that provide a competitive edge whereas other developments can be outsourced.

7.3 Advantages and disadvantages of outsourcing NPD
The participants were asked to determine the advantages and disadvantages of outsourcing NPD. The participants’ views on the possible advantages and disadvantages of outsourcing NPD are concluded below.

- **Advantages**
  - Reduction in cost or reduction in expenditure
  - Attaining high economies of scale
  - Freeing up of existing facility
  - It allows to concentrate on core competencies
  - Freeing up other resources

- **Disadvantages**
  - Less control over situation
  - Leakage of confidential data
  - Quality issues and problems
  - Slow response rate
  - Decrease in-house capacity

The participants were of the perception that there are few advantages that can still be achieved by the firm. The CPs stated that lowering costs, reducing the cash flow and improving the response rate can still be further achieved. On the other hand, disadvantages like protecting the leakage of data and obtaining high quality results have been already discussed within the firm. The CMs also had a similar point of view. Here by deterring the advantages and disadvantages the researchers have tried to link the decision-making and creating a competitive advantage for outsourcing NPD within the Indian pharmaceutical industry.

8. Conclusion and Further Research
The main aim of this research was to investigate the advantages and disadvantages of outsourcing NPD within the Indian pharmaceutical industry. There is an immense pressure on the pharmaceutical firms to improve quality, deliver performance and receptiveness. In reacting to these pressures, it is also a necessity to reduce cost; hence the firms are exploring new ways to respond to these pressures. The decision to make or buy a product is always a difficult decision that a firm must face.

Outsourcing new product development can be considered as a strategic decision to stay competitive in the global market. A successful outsourcing decision can prove to be very significant as it has many benefits associated with it. The results obtained in the qualitative case study show that outsourcing is not only about cost savings or reducing expenditures of the new product development process, but it is a method that allows an organisation to overcome its limitations. The other reason why more and more pharmaceutical companies are planning to outsource NPD is attaining flexibility to perform their core activities, fulfilling the expansion plans and creating innovation using new technologies.

There are few factors that companies need to consider while taking the outsourcing of NPD decision. One of them was determined to be the hidden costs involved while outsourcing new products. It is very important to calculate the hidden cost involved for a smooth outsourcing process. The participants also revealed that the time estimated by the firm for a new drug to be in the market is always greater than the assumed time. Thus it is very important to keep in consideration the above factors before taking an outsourcing decision.

It can be concluded from the findings of this study that outsourcing can create a sustainable competitive advantage. The advantages of outsourcing are numerous so as a result, the disadvantages can either be neglected or corrected using appropriate steps. There are many reasons that have been determined for pharmaceutical firms to outsource. This can be linked to support the contention that outsourcing can be first choice over in-house production. Though there has been very little evidence that outsourcing of NPD can provide a competitive advantage over rivals.

Thus from the research findings we are able to conclude that the outsourcing of NPD has both pros and cons associated with its function. Hence it could be determined that by taking correct outsourcing decisions can lead to a competitive advantage over internal production. The study thus helped to evaluate, why pharmaceutical firms have adopted the outsourcing of NPD, what key factors need to be considered while decision-making and how it can create a sustainable competitive advantage.

The study set to examine and evaluate the role of the various key drivers which play an influential role in outsourcing in India. This was achieved through a comprehensive questionnaire distributed to pharmaceutical companies who can be classified as contract manufacturers or contract providers. It can be concluded that while some contract providers may still be using local contract manufacturers and remain content with local service providers, unsatisfied contract providers who do not want to renew contracts may look offshore to meet their needs.

Finally, there is a broad opening to conduct future research on the related topic of outsourcing NPD within pharmaceutical industry. In particular, there is scope of future research to perform a quantitative research with facts and figures. It can be interesting to see the effects of outsourcing on the overall performance (i.e. measuring the performance of outsourcing so as to determine the effectiveness of the outsourcing decision). Also, there is opportunity to investigate the social side of outsourcing, for example, what goes into building a successful outsourcing relationship or partnership. A study about how outsourcing can lead to mergers and acquisition can also be conducted to understand the relationship between the contract manufacturers and the contract providers.

References

764