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Strategic and Operational Outsourcing – Decisions in the Pharmaceutical Industry

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Abstract

OEMs (Original Equipment Manufacturers) increasingly outsource (part of) their supply chains to contract manufacturers. Various benefits, reasons, risks, and theories on outsourcing have been developed, discussed, and analyzed in a wide body of literature. In this paper, we develop a framework of outsourcing research by providing a distinctive view on the (recent) outsourcing literature. We identify that little is known on outsourcing at the operational (planning) level and that in the quantitative (formal modelling) literature outsourcing is considered exclusively as a secondary external source in addition to the internal manufacturing source. To fill this gap and to contribute to the understanding of the operational implications of outsourcing, we conduct two extensive case studies into outsourced supply chains in the pharmaceutical industry, where the contract manufacturer is the only source of supply. Our main insight is that in an outsourcing relationship, the order process consists of different hierarchically connected decisions in time, hence requiring a richer and more developed communication and ordering pattern than is commonly assumed. These and additional insights show the complexity of outsourcing from an operational planning perspective. This understanding is essential to further develop supply chain decision support tools that explicitly incorporate outsourced operations.

Keywords

Outsourcing framework, Literature review, Case study, Pharmaceutical Industry, Supply Chain Planning

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1. Introduction

Outsourcing has been defined by Chase *et al.* (2004, p.372) as an 'act of moving some of a firm's internal activities and decision responsibilities to outside providers'. Outsourcing is a broad phenomenon and it can cover many areas and industries. In the last few years, many papers appeared on the development of outsourcing strategies in various industries, which also show that outsourcing is developing in many industries in the last few years. Abraham and Taylor (1996) provide evidence of rising outsourcing of business services in thirteen U.S. industries and Helper (1991) documents the increased outsourcing of parts in the U.S. automobile sector. A survey in 1997 of more than 600 large companies by the American Management Association finds that substantial numbers of companies are now outsourcing in many areas (information systems, finance, accounting, manufacturing, maintenance, and personnel). Among manufacturing companies, more than half had sourced out at least one component of their production process (Bryce and Useem, 1998).

Outsourcing decisions and strategies have been widely investigated and documented in the literature. In many papers, outsourcing has been mainly motivated by an economical trade-off to allow companies to focus on their core competences. The idea of focusing on core competences has been recognized in the strategy literature as a critical success factor in the long-term survival of a company (Prahalad and Hamel, 1990; Brandes *et al.*, 1997). Some papers consider the managerial implications of outsourcing, like the loss of control and the focus on core activities (Momme, 2002). Other papers focus on strategic implications (Quinn and Hilmer, 1994)), the financial and human resource implications (Lever, 1997) or the outsourcing of logistics functions to service providers (Rabinovich *et al.* (1999); Andersson and Norrman (2002)). Besides the motivations and implications of outsourcing, many papers have looked into the benefits of outsourcing (e.g. Jiang *et al.*, 2007) and the risks of outsourcing (e.g. Schniederjans and Zuckweiler, 2004).

Although some review papers (e.g. Kremic *et al.*, 2006) have sorted the literature on outsourcing in different ways, we are specifically interested in the distinction between strategic outsourcing decisions and operational control of outsourced operations. We develop a framework that organizes the literature accordingly and we bridge between two large streams within the literature: the stream of papers that develop insights based on qualitative studies (e.g. case studies or empirical work) and the stream of papers that develop insights based on quantitative studies (mathematical modelling). Based on this framework, we identify a gap in the literature on outsourcing. To our knowledge, nothing has been documented in the literature on outsourcing from an operational planning level, i.e. the operational implications of outsourcing and how to plan and control outsourced operations on an operational planning level. Given that an OEM has outsourced part of its supply chain to a contract manufacturer, how to plan and control this supply chain? How to incorporate the outsourced operations in the OEM's supply chain planning models? These are questions that remain unanswered in the literature.

Based on this gap in the literature, we conducted two extensive case studies at three pharmaceutical companies to get practical insights into the operational side of outsourcing of production activities. The case studies show the complexity of outsourcing from an operational planning perspective. The insights gathered from the case studies are contributing to the (lacking) knowledge on operational control of outsourcing and they are helpful to incorporate outsourced operations in the supply chain planning modelling, as the supply chain planning models mostly assume that the production is performed in-house (e.g. De Kok and Fransoo, 2003).

This paper is organized as follows. In the next section, we develop a framework based on the literature on outsourcing, where we bridge between the quantitative and qualitative parts of the literature and where we distinguish between studies that have looked into strategic

outsourcing and papers that studied operational outsourcing. Section 3 discusses the case studies and subsequently, section 4 discusses the main insights that we gathered from the case studies and shows the theoretical contribution of this paper. Then, section 5 draws some conclusions.

2. Qualitative and quantitative insights into strategic and operational outsourcing

Some papers have reviewed the literature on outsourcing and developed decision frameworks, mainly as a support for managers to assist them in the outsourcing decision process (Kremic *et al.*, 2006; Fill and Visser, 2000; Razzaque and Sheng, 1998).

Kremic *et al.* (2006) give an excellent review of the literature on outsourcing and develop a framework to classify whether the considered papers address outsourcing benefits, risks, motivations or factors. One of the main insights from this paper is that most studies focus on US-profit organizations and are typically theoretical, discussing benefits, risks and motivators. Research on outsourcing of non-profit organizations is found to be scarce. Further, the paper provides an interesting overview of the reasons for outsourcing, which can be summarized in three main blocks: cost, strategy, and politics. Based on a survey of more than 1,200 companies, Deavers (1997) identifies five main reasons for outsourcing: improving company focus, accessing world-class capabilities, acceleration of benefits from reengineering, sharing of risk and freeing of resources for other purposes.

We refer the reader to Kremic *et al.* (2006) for a detailed description of motivations, benefits, and risks of outsourcing. Our framework can partly be considered as an extension of this work, as Kremic *et al.* (2006) do only consider strategic outsourcing decisions, i.e. whether to outsource and which organization's function to outsource, whereas in our framework, we also include papers that study outsourcing on the operational planning level. Razzaque and Sheng (1998) review the literature on the outsourcing of logistics functions to third party logistics service providers. Fill and Visser (2000) review the literature on outsourcing and present an outsourcing decision framework, which consists of three main components: the search for the unique contextual factors, the strategic implications of outsourcing, and the cost aspect.

In this section, we structure the recent literature on outsourcing in two ways. First, we distinguish between papers that provide qualitative insights (based on a literature review, empirical or case studies) and papers that provide quantitative insights (based on mathematical modelling). We did not find the combination of these two streams of literature in earlier work. Second, we distinguish between papers that consider outsourcing on a strategic level and papers that consider outsourcing on an operational level. Considering outsourcing on a strategic level means that the paper is addressing the outsourcing decision, i.e. whether to outsource or not or related issues. Papers that consider outsourcing on an operational level address questions that follow after the outsourcing decision. Examples of these questions are the quantities to be ordered at the contract manufacturer or the planning implications of outsourcing.

2.1. Outsourcing on the strategic level

Since the large majority of the papers on outsourcing consider outsourcing on a strategic level, we distinguish this large body of literature into papers that mainly consider the motivation for outsourcing, the process of outsourcing, and the result of outsourcing. Table 1 shows the framework and the classification of the considered papers. It is not our objective to capture the whole literature of outsourcing, as the topic has received a lot of attention in various parts of the literature (e.g. Kremic *et al.*, 2006), but we mention papers from different streams in the literature to have as much as possible a representative overview of the (recent) literature to be able to draw valid conclusions. We refer the reader to the references of the

papers to have a more complete list of papers. Below, we will discuss the papers more in detail and show the insights that follow from these papers.

Table 1. A framework for outsourcing literature

		Qualitative insights	Quantitative insights
Strategic level	**Motivation**	**Box 1.** Holcomb and Hitt (2007); Lankford and Parsa (1999); Quinn and Hilmer (1994); Sanders *et al.* (2007)	**Box 4.** Cachon and Harker (2002); Tsai and Lai (2007); Van Mieghem (1999)
	Process	**Box 2.** Amaral *et al.* (2006); De Boer *et al.* (2006); Kotabe *et al.* (2007); Momme and Hvolby (2002); McIvor (2000); Vining and Globerman (1999)	**Box 5.** Balakrishnan *et al.* (2007); Ngwenyama and Bryson (1999); Schniederjans and Zuckweiler (2004)
	Result	**Box 3.** Berggren and Bengtsson (2004); Brandes *et al.* (1997); Bryce and Useem (1998); Jiang *et al.* (2006); Jiang and Qureshi (2006); Marshall *et al.* (2007); Rabinovich et al. (1999)	**Box 6.** Kamien and Li (1990); Gorg and Hanley (2005); Abdel-Malek *et al.* (2005)
Operational level		Not available	**Box 7.** Bertrand and Schridharan (2001); De Kok (2000); Kim (2003); Lee *et al.* (2002); Kouvelis and Milner (2002); Yang *et al.* (2005); Boulaksil and Fransoo (2007)

2.1.1. Motivation for outsourcing

Qualitative insights

Holcomb and Hitt (2007) discuss two main theories on outsourcing. The Transaction Cost Theory (TCT) has been the dominant theory that explains outsourcing as an economic approach that achieves cost efficiencies by assigning transactions to different governance mechanisms. The second theory has been described by more recent research that use the Resource Based View (RBV) to examine the role of specialized capabilities as a potential source of value creation in relationships between firms. The authors argue that only limited applications of TCT and RBV are available in the operations management field and they extend both perspectives to explain conditions leading to strategic outsourcing.

Quinn and Hilmer (1994) discuss strategies to determine what a firm's core competencies are and which activities are better performed externally, i.e. outsourced to contract manufacturers. Sanders *et al.* (2007) present a framework of outsourcing engagements, their characteristics, and variations. They argue that the selection of an outsourcing strategy should be flexible and dynamic, rather than a rigid and static decision process. Based on multiple interviews they conducted, they warn for many hidden costs of outsourcing.

Based on the set of papers in Box 1 of the framework (see table 1), one can conclude that there are mainly two motivators for outsourcing: cost (Holcomb and Hitt, 2007) and strategy (Quinn and Hilmer, 1994; Sanders *et al.*, 2007). We refer the reader to Deavers (1997) and Kremic *et al.* (2006) for a more complete overview of reasons for outsourcing. Many papers discuss a firm's wish to save costs as a motivation for companies to outsource (e.g. Vining and Globerman, 1999). Outsourcing for cost reasons can occur when the contract manufacturer is so specialized or benefits from economies of scale such that the contract manufacturer's fee

plus the transaction costs is still lower than producing in-house (Holcomb and Hitt, 2007). Beside costs, strategic reasons are also very often mentioned as reason for outsourcing, like focusing on core competencies (Quinn and Hilmer, 1994) or the need for greater flexibility to manage demand uncertainties (Lankford and Parsa, 1999).

Quantitative insights

Cachon and Harker (2002) present a model of competition between two firms that are allowed to outsource and that face scale economies, which means that the cost per unit of demand is decreasing in demand. They show that the lower cost firm (in equilibrium) may have a higher market share and a higher price. The authors show that the firms will strictly prefer to outsource and conclude that scale economies provide a strong motivation for outsourcing even if outsourcing provides no cost advantage.

Tsai and Lai (2007) consider the situation where firms have to either expand their capacities or to outsource, as the market demands exceed the company's production capacity. They develop an Activity Based Costing decision model which incorporates capacity expansions and outsourcing features, by using a mathematical programming approach. With this model, the firms can evaluate the benefits of expanding the various kinds of capacity and outsourcing simultaneously and the model helps the firms to decide about capacity expansion or outsourcing.

Van Mieghem (1999) values the option of outsourcing to improve financial performance and supply chain coordination by analyzing a stochastic competitive game where the outsourcer and contract manufacturer decide separately on their capacity investment levels. The author analyzes and presents outsourcing conditions for three different contract types and shows that the option value of outsourcing increases as markets are more volatile or more negatively correlated.

2.1.2. The outsourcing process

Qualitative insights

Momme and Hvolby (2002) study the process of outsourcing and propose a framework which indicates the interfaces between the production system and internal support functions to determine the cross-functional interdependencies of the outsourcing process. The framework consists of four phases of outsourcing with in each phase the key activities, performance measures and expected output.

De Boer *et al.* (2006) develop a conceptual model that assists firms in structuring the outsourcing process. In particular, they consider the decision as to which activities seem most suitable for outsourcing and which type of supplier should be used.

Amaral *et al.* (2006) conduct audits and interviews in numerous industries and discuss some (observed) risks that are associated with the outsourcing process. The authors propose and analyze strategies for preventing some of these risks when outsourcing production. The main message is that only by investing in processes and information systems to manage the contract manufacturers and prevent abuses of the relationship, the OEM can safeguard the promise of outsourcing.

Vining and Globerman (1999) help managers to identify the pre- and post-contractual risks associated with outsourcing decisions along with strategies that can be implemented in the pre-contractual stage in order to mitigate those risks.

Kotabe *et al.* (2007) argue that there is an optimal degree of outsourcing. The outsourcing-performance relationship takes on an inverted-U shape, implying that as firms deviate further from their optimal degree of outsourcing, by either insourcing or outsourcing too much, their performance will suffer disproportionately.

Quantitative insights

Balakrishnan *et al.* (2007) examine the phenomenon of outsourcing front-end business processes in supply chains. Incomplete information leads to firms preferring to outsource their back-end rather than their front-end processes. However, the analysis in this paper shows that the effect of incomplete information can be limited under several conditions. The decision to outsource front-end tasks should also take into account the nature of customer contact and the information intensity. If the contact is symbolic and the information intensity is high, then there is greater potential for outsourcing such tasks.

Ngwenyama and Bryson (1999) build upon transaction cost theory and present an approach to modelling the key aspects of single- and multi-vendor outsourcing strategies. They show how the decision maker can model each strategy to find the minimum cost and maximum possible profit for each strategy. Another contribution of this paper is the ability to determine which of the outsourcing options are superior given prevailing conditions.
Schniederjans and Zuckweiler (2004) focus on the risk of outsourcing when it takes place between business organizations in different countries or in an international context. They present a model that includes international risk factors in the outsourcing-insourcing decision, which should help the management in making a decision whether a company should undertake international outsourcing or just maintain their domestic operations.

2.1.3. The result of outsourcing

Qualitative insights

Berggren and Bengtsson (2004) look at the actual outcomes of outsourcing at two leading telecom firms (Nokia and Ericsson). The comparison reveals different strategies for production and outsourcing. The authors state that besides the cost advantages, which are often the key driver for outsourcing, firms also have to consider the costs of transferring products, equipment, and knowledge to the contract manufacturer. Their case studies show that considering these aspects might have led to a strategy that combines external sourcing and in-house production rather than complete outsourcing for the considered firms.

Brandes *et al.* (1997) perform five case studies in which they focus on the result of the outsourcing decision, i.e. whether the outsourcing was successful or not. They conclude that a combination of focus on a core competence, cost efficiency, and high commitment in the outsourcing process contribute to successful outsourcing, whereas financial problems, low commitment in the outsourcing process, and a lack of competences at the outsourced unit contribute to failed outsourcing.

Marshall *et al.* (2007) present findings from an analysis of the experiences of three telecommunication companies that have outsourced extensively. The authors determine the key influences on the outsourcing process and the outsourcing outcomes in the three case companies. The findings mainly show that those companies that developed collaborative relationships with their suppliers achieved higher levels of success with outsourcing.

Jiang and Qureshi (2006) study the result of outsourcing and show that there are three main gaps in the literature on outsourcing: lack of objective metrics for outsourcing results evaluation, lack of research on the relationship between outsourcing implementation and firms' value, and lack of research on the outsourcing contract itself.

Jiang *et al.* (2006) empirically investigate the effect of outsourcing on firm level performance. They show that outsourcing can improve a firm's cost efficiency, but there is no evidence that outsourcing improves firm's productivity and profitability.

Jiang *et al.* (2007) study the relation between firms' market valuation and outsourcing decisions by using a cross-sectional valuation approach. Results based on Japanese manufacturing industries data from 1994 to 2002 indicate that core business-related outsourcing, offshore outsourcing, and shorter-term outsourcing have positive effects on outsourcing firms' market value.

Rabinovich *et al.* (1999) perform a large survey at logistics managers in different industries and show that firms can improve customer service and reduce costs by outsourcing multiple logistics functions.

Quantitative insights

Kamien and Li (1990) present a multi-period game-theoretic aggregate planning model with given capacity constraints and show that the option of subcontracting results in production smoothing.

Gorg and Hanley (2005) examine the effect of international outsourcing on productivity at the company level, based on data from the electronics industry in Ireland. The effect of international outsourcing on company level productivity turns out to be dependent on the nature of the outsourced inputs (services or tangibles) and on the company's export intensity. Outsourcing of materials provides significant productivity gains, but this effect holds only for plants with low export intensities.

Abdel-Malek *et al.* (2005) develop a framework to compare outsourcing strategies in multi-layered supply chains. They determine the needed amount of safety stocks as a measure to compare the different outsourcing strategy options to the management. For the safety stock determination for each outsourcing strategy, the supply chain has been modelled a series of tandem queues to determine the lead times which give an estimate to the needed safety stocks.

2.2. Outsourcing on the operational level

The second part of our outsourcing framework considers outsourcing on the operational (planning) level. Several quantitative studies have been conducted on outsourcing on the operational level. We discuss some of these papers.

Quantitative insights

Lee *et al.* (2002) present a model in which each customer order has a due date and an outsourcing option is available. The model decides on the best machine selection for each operation, the sequence of operations, the operations to be outsourced, and minimizes the makespan for the due date of each order. The model is solved by a genetic algorithm heuristic approach.

Kouvelis and Milner (2002) study the interplay of demand and supply uncertainty in capacity and outsourcing decisions in multi-stage supply chains. They study how non-stationary stochastic demand affects the outsourcing decisions and focus on how changes in supply and demand uncertainty affect the extent of outsourcing. One of the insights from this paper is that greater supply uncertainty increases the need for vertical integration while greater demand uncertainty increases the reliance on outsourcing.

Bertrand and Sridharan (2001) study a situation where the order arrival rate at a certain firm is greater than the service rate which makes subcontracting necessary. They develop four heuristic decision rules with varying informational needs and complexity to determine when and which orders should be subcontracted. One of the main insights of this paper is that decision rules that do not use shop-workload information in making the subcontracting decision are performing worse than the rules that do use that information.

Yang *et al.* (2005) study the optimal production-inventory-outsourcing policy for a firm with Markovian in-house production capacity that faces independent stochastic demand and has the option to outsource. They show under particular circumstances and assumptions what a good performing production and outsourcing strategy is.

De Kok (2000) considers periodic review order-up-to policies and proposes two capacity reservation strategies. The first strategy assumes that excess capacity needs are postponed and the second strategy assumes that excess capacity needs are outsourced. The objective is to find the optimal policies for the two strategies to find the best reservation policy.

Boulaksil and Fransoo (2007) propose and compare three different order release strategies to control outsourced operations in a supply chain. The order release strategies differ in the number of decision levels in the order release system. By simulation studies, the authors show that the order release system with multiple decision levels (i.e. more sophisticated) performs significantly better than the order release system with only one decision level.

2.3. Insights from the literature

In this section, we introduced and discussed the framework that considers strategic and operational outsourcing. We have seen that outsourcing decisions and strategies have been widely investigated and documented in the literature, but mainly from a strategic level. The body of literature on strategic outsourcing is enormous. The main research questions addressed in that part of the literature are theories behind outsourcing (e.g. Holcomb and Hitt, 2007), whether to outsource or not and related issues such as: the risks that are associated with outsourcing (Schniederjans and Zuckweiler, 2004), the conditions for successful outsourcing (Van Mieghem, 1999), which activities to outsource (e.g. Quinn and Hilmer, 1994; Balakrishnan *et al.* 2007), how much to outsource (Kotabe *et al.*, 2007) and the results of outsourcing (e.g. Berggren and Bengtsson, 2004; Brandes *et al.*, 2007). All the papers in this stream of the literature assist the manager in taking the outsourcing decision, i.e. whether to make-or-buy, whether to perform the production indoors or to whether to purchase the materials externally.

The literature on outsourcing on the operational level, which deals with outsourcing after having made the outsourcing decision, is found to be scarcer. Once a firm has made the outsourcing decision, the outsourced operations need to be planned and controlled. The studies that appeared on outsourcing on the operational level are all quantitative studies, where mathematical models have been developed which incorporates outsourcing, whereas (to our knowledge) *no* studies are documented in the literature that have looked into outsourcing on the operational level from a qualitative perspective. This gap is quite remarkable given the enormous amount of literature on outsourcing. Therefore, based on the framework that we developed, we introduce the following proposition.

Proposition 1: The literature on outsourcing lacks (qualitative) insights on the effect of outsourcing on the operational planning level.

The quantitative studies that appeared on outsourcing on the operational level consider outsourcing as an option *next to* the internal production system, i.e. part of the production is outsourced to a contract manufacturer next to internal production to achieve a certain

objective, mostly to cover excess demand (De Kok, 2000; Bertrand and Sridharan, 2001) or to deal with uncertainties (Kouvelis and Milner, 2002). In Lee *et al.* (2002), outsourcing is also an option next to the internal production system to control the delivery performance to customers. Therefore, we develop the following proposition.

Proposition 2: The quantitative studies documented in the literature on outsourcing on the operational level consider outsourcing as an option next to the internal production system (dual sourcing), where the outsourcing option is introduced, i.e. included in the model to mainly cover excess demand, to deal with (demand) uncertainties or to control the delivery performance towards customers.

By developing the outsourcing framework, we are able to identify a gap in the literature (see proposition 1). Moreover, we have seen that in the quantitative studies on the operational level, outsourcing is considered as an option next to the internal manufacturing. Therefore, there is a need to gather qualitative insights on outsourcing on the operational planning level. Furthermore, outsourcing should also be studied without considering it as a valve to meet a certain objective(s), but in the case the contract manufacturer is the *only* source for performing the production activities. To (contribute to) fill(ing) these gaps in the literature, we performed two extensive case studies to gather (qualitative) insights on outsourcing, i.e. the implications of outsourcing on the operational planning level, *given* that the contract manufacturer is the only supplying source.

3. Case studies

3.1. Motivation and methodology

Based on the framework that we developed in the previous section, we identified gaps in the literature on outsourcing, which are expressed in propositions 1 and 2. To fill these gaps, we performed two extensive case studies at three pharmaceutical companies to get some practical insights on outsourcing on the operational level and to build some theory on operational outsourcing. As suggested by Yin (1994), the use of case studies is typical in the first theory development stages, when investigating events or phenomena that have little or no theoretical background and no a priori theory can be identified to select case studies and the constructs to be examined. The case study methodology that we use in our studies is similar to that of Yin (1994) and Voss *et al.* (2002).

Some papers have appeared in the literature that discuss planning issues in the pharmaceutical industry (Ashayeri and Selen, 2003; Papageorgiou *et al.*, 2001; Sundaramoothy and Karimi, 2004; Grunow *et al.*, 2003), but all these papers assume that the production is performed in-house and no outsourcing is considered.

Sundaramoothy and Karimi (2004) do develop a model in which they consider production outsourcing in the pharmaceutical industry, but they address the strategic question whether to undertake the production of a new product in-house or whether to outsource it to a contract manufacturer. This paper considers outsourcing, but it has mainly been approached from a strategic point of view, as outsourcing is not studied as such, but used a strategy to make the introduction of new products more attractive.

Besides the production outsourcing in the pharmaceutical industry, there are some studies that consider the outsourcing of research and development activities. Since the pharmaceutical industry is characterized by a large amount of such activities, most papers on outsourcing within this industry deal with the outsourcing of these activities (Higgins and Rodriguez (2006); Jones (2000); Piachaud (2002)). Since these papers are out of the scope of our study, we will not discuss them in more detail.

The choice for the pharmaceutical industry seems to provide a perfect context to identify exemplar cases, as outsourcing and outsourced supply chains are not yet documented and they are rapidly developing in this industry. Several studies show that the total revenues of contract manufacturers in the pharmaceutical industry rise on average by approximately 13% per year (see e.g. Business Insights, 2005). Furthermore, Lurquin (1996) already noticed that supply chain optimization is one of the strategic issues that the pharmaceutical industry will face in the coming years and Shah (2004) also remarked that supply chain optimization and optimal planning is a major research theme in the pharmaceutical industry and it did not receive due attention. He shows that the use of contract manufacturers forms a source of complexity, as it extends the supply chain coordination problems. The case studies that we describe in this paper intend to contribute to this line of research.

The case studies were conducted from January 2006 till March 2007. During this period, we were positioned at the outsourcer (the company that outsourced the production activities) and we have regularly visited the contract manufacturers. Further, several managers and planners at different hierarchical levels of the companies were regularly interviewed. To ensure reliable results, multiple sources of evidence were used. Therefore, besides the interviews, we also performed an extensive documentation study, data analyses, looked into archival data, such as the contracts, and did direct observations.

We are aware that care is needed in drawing general conclusions from case studies, as the analysis is based on a limited number of cases. Despite this, case studies can have high impact and can lead to new insights (Voss *et al.*, 2002). Many concepts and theories that are documented in the literature of operations management (e.g. lean manufacturing) have been developed from case studies.

3.2. Two case studies

In this section, we describe the two case studies that we performed at three different companies (one outsourcer and two contract manufacturers) that operate in the pharmaceutical industry. We mainly focus on the planning process between the outsourcer and the contract manufacturers and the main implications of controlling the outsourced operations. The outsourcer is a research- and development based worldwide operating pharmaceutical company with a global presence in branded prescriptive products. This company plans and controls its global supply chain integrally and has implemented a so-called Advanced Planning and Scheduling tool (Stadtler and Kilger, 2005) to support this. This outsourcer has outsourced some production activities to two contract manufacturers; one is located in Germany and the other one in the United States. The contract manufacturers do not have their own product portfolio, but produce products by providing outsourcing services for other companies (the outsourcers).

In these cases, the outsourcing decision has been made in the past and outsourcing relationships are in this industry typically long-term, as very costly and time-consuming approvals are needed from several authorities to be able to produce at the contract manufacturer. Therefore, the outsourcer and the contract manufacturer typically go for long-term relationships. The outsourcer faces the problem of how to plan and control the outsourced operations. Therefore, insights on outsourcing on the operational level are crucial. In the next two sections, we discuss the case studies in more detail. For confidentiality reasons, we cannot mention the names of the companies or the products.

3.2.1. Case study 1

In this case study, we consider the case where the outsourcer has outsourced the production of product A, one of the outsourcer's strategic products, to contract manufacturer CM1, who is located in the United States. This product is a tablet and there are three variants of this tablet,

which differ in the strength of the tablet, i.e. the amount of active ingredient in the tablet. The tablets are sold in boxes that consist of a number of blisters. Each blister contains six tablets. These tablets have a very specific serving method, which is patented and owned by contract manufacturer 1 (CM1). Therefore, in this case, the outsourcer was forced to outsource the production activities to this contract manufacturer, who produces several products for several customers on the same production line. That means that the contract manufacturer's production line is not dedicated to this particular outsourcer, which makes it hard for the outsourcer to order a feasible quantity at the contract manufacturer. This issue will be discussed later more in detail, as it forms one of the main difficulties of planning this supply chain.

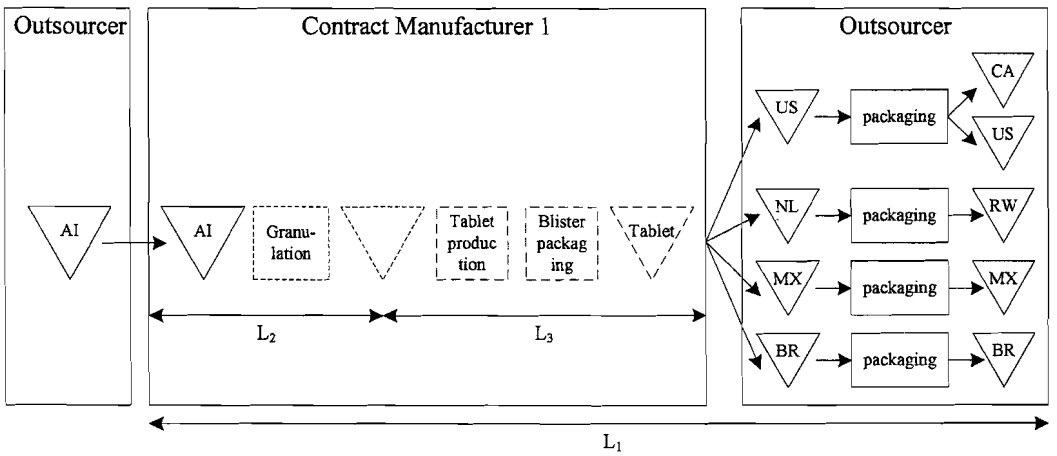

Figure 1. The supply chain of product A

Figure 1 shows the supply chain (goods flow) of product A. A triangle represents a stockpoint and a box a production unit. The intermittent part of the figure shows the part of the supply chain that is out of the sight of the outsourcer. The outsourcer produces the active ingredient (AI) and sends it to the contract manufacturer. The output of the contract manufacturer's production process is blistered tablets. Then, these tablets are sent to one of the four outsourcer's packaging sites, which are located in the United States, the Netherlands, Mexico, and Brazil. These sites pack the blistered tablets and send them to the several national warehouses (the most downstream stockpoints), which are located in Canada (CA), United States (US), MX (Mexico), BR (Brazil), and the rest of the world (RW). These national warehouses keep inventories of the finished products and are responsible for selling the products to the outsourcer's customers.

The contract manufacturer's production process starts with the granulation of the active ingredient. The granulated material is stocked at the intermediate stockpoint. Then, the tablet production process starts and immediately thereafter, the tablets are blistered and country specific text is printed on the blister. Therefore, the contract manufacturer's production process is driven by orders from the outsourcer. These orders are first grouped by the planner (of the outsourcer), as this person is responsible for releasing orders towards the contract manufacturer. The total order lead time for orders from the national warehouses is L_1 time periods (22 weeks).

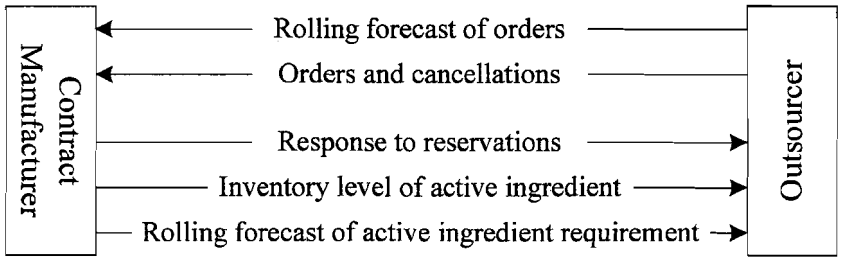

Figure 2. Information flow between the two parties

Figure 2 shows the information flow between the two parties. The two parties agreed upon communicating these data in the contract. At the beginning of each planning cycle, which is equal to one month, the outsourcer provides the contract manufacturer a 12-months rolling forecast of the outsourcer's requirements, which is based on the demand forecast of end products. These forecasts are basically *reservations* of capacity slots by the outsourcer, which can be either accepted, changed or cancelled by the contract manufacturer. As we discussed earlier, the contract manufacturer serves multiple customers on the same production line. Since the customer's demand is uncertain, it might be that the cumulative reserved quantities by all customers exceed the contract manufacturer's capacity, which results in some rejections or changes of the reservations. Another reason for sharing the demand information is the fact that other additive materials are needed for producing the tablets. CM1 is responsible for ordering these materials, and therefore getting forecast data from the customers is crucial to control the supply of the additive materials.

Once a reservation is accepted, it is considered as an order commitment until the outsourcer later (lead time periods before the delivery date) communicates the final orders, which should not deviate more than a predefined amount from the reserved quantities. The outsourcer places orders with a minimum of 90 days lead time before the delivery is required. The contract manufacturer has the right to reject any orders in which the delivery date is earlier than 90 days. However, even after placing the order, the outsourcer has the option to change the ordered quantity up to L_3 periods (=45 days) before the delivery date, i.e. before the tablet production starts (see figure 1). The change (in ordered quantity) is limited to the range between -10% and +25%. In the case the outsourcer decreases the ordered quantity by more than 10%, the outsourcer pays the contract manufacturer a cancellation fee of 30% of the value of the products cancelled.

Further, at the beginning of each planning cycle, the contract manufacturer shares with the outsourcer the inventory data of the active ingredients. These data are needed by the outsourcer to plan its supply chain properly. However, it turns out that in practice that this contract manufacturer is always too late with sharing these data, which means that the outsourcer bases the inventory data on an estimate, which is made by subtracting the received quantities from the last shared inventory data. This estimate can deviate from the real inventory level due to varying yields and quality rejections.

The last flow of information between the parties is the 12 forthcoming months rolling forecast of the requirement of active ingredients that is communicated by the contract manufacturer towards the outsourcer. It is quite strange that the contract manufacturer communicates these data, because the contract manufacturer determines these quantities based on the rolling forecasts that are sent by the outsourcer.

The information flow, as shown in figure 2, is agreed in the contract between the outsourcer and the contract manufacturer. Besides the information flow agreements, there is also a volume agreement between the parties. The contract manufacturer commits an annual manufacturing capacity of X million tablets. If the outsourcer does not order in a year an

amount which is at least 90% of the committed capacity, the outsourcer pays the contract manufacturer a capacity reservation fee multiplied with the difference between the committed capacity level and the actual amount ordered for delivery in the same year. If the outsourcer fails to utilize a minimum of 80% of X in a given year, then a new lower capacity will be agreed to by the parties for the future years, without any penalty fee.

Apart from the volume agreement, a performance agreement (delivery reliability) is also in the contract that sets that if the contract manufacturer delivers an order 20 days after or 10 days before the delivery date, the contract manufacturer has pay to the outsourcer a penalty fee of 1% of the value of the products for that delivery for each day that such order is late or early (with a maximum of 20% of the value of the outsourcer's order). From the other side, if the outsourcer fails to deliver the active ingredients in sufficient quantities to the contract manufacturer, then the outsourcer will be charged with a fee per tablet if the delay resulted in idle time of allocated machine capacity.

The outsourcer measures the delivery reliability of the contract manufacturer by the following measure: number of orders shipped within the promise date (-15 days to 0 days) over the total number of orders promised to ship. Based on a data analysis, it turns out that the delivery reliability was about 27% in 2005. This has mostly to do with the continuous changes the outsourcer makes in the orders that are placed at the contract manufacturer. In section 4, we will discuss this in more detail.

3.2.2. Case study 2

In this case study, we consider the case where the outsourcer has outsourced the production of product B to contract manufacturer CM2, who is located in Germany. Product B is a parenteral product (a liquid in which the active ingredient is dissolved) and it is also considered as one of the outsourcer's strategic products. Product B has three variants that differ in the concentration of the liquid. In contrast to the previous case, CM2 does not own a patent for a certain technology to produce product B, but in this case, the outsourcer benefits from the capacity pooling effect at CM2, who produces several products for several customers on the same production line. That means that the outsourcer does not know in advance which part of the capacity is available for the production of product B. Neither does CM2 know that exactly in advance, as CM2 first collects all demand data (orders) of all customers and in the case of a capacity shortage, some changes or rejections will be issued towards the customers. This is actually the same situation as in case study 1 and we will discuss this issue in more detail in the next section, as it forms one of the main difficulties of planning outsourced operations in a supply chain.

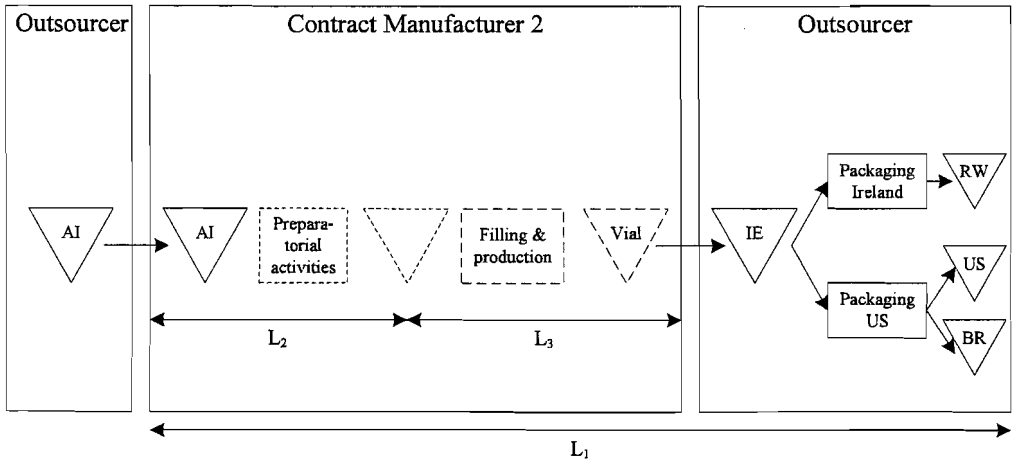

Figure 3. The supply chain of product B

Figure 1 shows the goods flow of product B. The outsourcer produces the active ingredient (AI) and sends it to CM2, who produces vials with the liquid in which the active ingredient is dissolved. For this production process, CM2 also needs additive materials which are ordered by CM2. The output of the contract manufacturer's production process is vials, which are sent to the outsourcer's production site in Ireland. This site ships the vials to the packaging site in the US, which packs the vials for the national warehouses in Brazil and the United States. Further, the site in Ireland packs the products for all other national warehouses (RW). The national warehouses keep inventories of the finished products and sell the products to the outsourcer's customers, which are mostly hospitals, pharmacies or wholesalers.

The contract manufacturer's production process starts with some preparatory activities, which are weighting, compounding and filtration of the required materials for the production process. After the preparatory activities, the materials are stocked at the intermediate stockpoint. Then, the filling of the liquid starts and some other processes follow, after which the vials are ready to be shipped to the outsourcer.

In contrast to the previous case, the formal contract between the outsourcer and CM2 describes only two agreements from a logistics point of view. The first agreement is that the contract manufacturer will undertake the manufacturing after receiving an order from the outsourcer. The second agreement is that the contract manufacturer will supply the vials to the outsourcer and that the outsourcer will pay for all products for which orders have been placed. So, the formal contract does not describe volume agreements or agreements on the logistics performance or penalty for any failure. However, there is an informal document of one page that describes some informal agreements. The informal agreement describes the fact that the outsourcer shares on a monthly basis accurate and timely demand forecasts with a horizon of 18 months. Further, the informal agreement also describes that CM2 is responsible for ordering the additive materials that are needed for the production of the vials.

The contract manufacturer's production process is driven by orders from the outsourcer. The lead time for orders from the contract manufacturer's production process (i.e. $L_2 + L_3$ in figure 3) is 20 weeks. The information flow between the two parties shows similarities with the previous case. At the beginning of each planning cycle, which is equal to one month, the outsourcer provides the contract manufacturer a 18-months rolling forecast of the outsourcer's requirements, which is based on the demand forecast of end products. These forecasts are basically reservations of capacity slots by the outsourcer, which can be accepted, changed or cancelled by the contract manufacturer as a result of his capacity planning.

Once a reservation is accepted, it is considered as an order commitment till the outsourcer later (lead time periods before the delivery date) communicates the final orders, which should not deviate from the reserved quantity. In this case, no limits are defined for the deviation, which means that the outsourcer can change or even cancel orders. Table 2 shows the amount of orders that have been changed or cancelled in the period June 2006 – February 2007. The first column shows the total amount of orders that have been placed at the contract manufacturer. Out of this total number of orders, the second column shows the number of orders that have been changed, the third column shows the number of new orders that have been issued, and the fourth column shows the number of orders that have been cancelled. A change of an order means that the delivery date or the ordered quantity has been changed.

Table 2. The number of changes in the orders placed at CM2.

	Number of orders	**Number of changes**	**Number of new orders**	**Number of cancellations**
June 2006	38	10	0	0
July 2006	60	13	5	3
August 2006	62	57	7	8
September 2006	62	7	0	3
October 2006	64	28	1	2
November 2006	64	18	0	9
December 2006	63	31	3	7
January 2007	45	6	0	2
February 2007	46	7	2	5

Contract Manufacturer 2 also shares with the outsourcer the inventory data of the active ingredients which is needed by the outsourcer to plan its supply chain properly.

4. Insights from the case studies

In the previous section, we discussed two cases where a pharmaceutical company outsourced the production activities of two different products to contract manufacturers. These case studies described the supply chain structure of the outsourced operations, the agreements between the parties, and the information flows between the parties. The aim of this paper is to provide insights into the outsourcing relationship and the main difficulties of planning outsourced operations in supply chain planning models. These insights will be discussed in this section.

Many papers that deal with outsourcing or contract manufacturing consider a buyer-supplier relationship with the contract manufacturer, which means that the contract manufacturer is the supplier of some products for the outsourcer. See e.g. Lankford and Parsa (1999) who state that outsourcing is the 'procurement of products or services from sources that are external to the organization'. In the case studies that we performed, we have seen that there is a supplier-buyer-supplier relationship, which means that the outsourcer is not only the buyer of the contract manufacturer, but also the supplier of the main materials for the contract manufacturer. This makes the relationship more complex, as the contract manufacturer does not only receive orders from the outsourcer, but places also orders at the outsourcer to receive the main materials and we have not seen this documented in the literature. An advantage of the supplier-buyer-supplier relationship is that both parties have an incentive to share relevant data to eliminate inefficiencies in the supply chain.

Proposition 3: An outsourcing relationship is not necessarily a buyer-supplier relationship, but can be also a buyer-supplier-buyer relationship.

The second insight follows from the fact that the contract manufacturer produces on the same (capacitated) production line for multiple customers, as outsourcing is mostly beneficial due to capacity pooling effects at the contract manufacturer. Further, the contract manufacturer faces stochastic demands from all his customers and faces the task to allocate the capacity to the customer's demand. This task is executed by the contract manufacturer independently. When the contract manufacturer faces capacity shortages, i.e. when customer demands are higher than the available capacity, the contract manufacturer allocates the shortages based on priorities that are unknown to the customers. These shortages result in rejections of or changes in the customer's orders, which complicates the order release strategy of the customers.

From the other side, the outsourcer, who modelled the outsourced operations in his Advanced Planning and Scheduling tool (Stadtler and Kilger, 2005) as a resource with a known fixed capacity level, faces the problem of releasing the optimal quantities, as due to possible capacity shortages, a probability exists that some orders will be changed or even rejected. The way the outsourcer has modelled the contract manufacturer's capacity level, i.e. as a resource with a certain known capacity level, is (as the case studies show) incorrect, which results in infeasible order quantities released towards the contract manufacturer.
We have seen in the case studies that this way of modelling results in a nervous ordering behaviour of the outsourcer, i.e. a lot of changes in the orders are issued to react on the behaviour of the contract manufacturer. In case 2, we have quantified this behaviour by showing the number of changes that are issued over a period of nine months and in case 1, this behaviour mainly led to the poor performance of the contract manufacturer.

Proposition 4: Outsourcing can be beneficial due to capacity pooling, which results in producing on non-dedicated production lines. Therefore, modelling the contract manufacturer's capacity as an internal production system, i.e. with a fixed known capacity level is incorrect.

Both cases show that the contract manufacturer produces several variants of the product, which differ in the concentration of the active ingredient in the variant. This results in medicines with different strengths, which is very common in the pharmaceutical industry. Actually, product differentiation is also known in other industries. In both case studies, we have seen that the production process at the contract manufacturer can be divided into two parts: the first part that is not variant dependent and the second part that is variant dependent. However, the outsourced part of the supply chain is completely order driven, which means that the outsourcer reserves and orders in batches per variant, whereas the outsourcer can basically *postpone* this decision till the second part of the production process starts at the contract manufacturer. This turns out to be very beneficial, assuming that the forecast accuracy improves as the forecast horizon gets shorter. Boulaksil and Fransoo (2007) perform a simulation study that shows that the postponement strategy substantially improves the supply chain performance in terms of total supply chain inventories.

The order release strategy gets more complicated with the cancellation option. After placing orders by the outsourcer, the outsourcer gets the opportunity to change the order quantities or the mix of the variants, as the variant specific part of the production process has not started yet. In practice, it turns out that the outsourcer even cancels some batches without any penalties. In case 1, the change is limited partly by the contract, whereas in the second case, the outsourcer can formally change limitless. This is accepted by the contract manufacturer, because the contract manufacturer is mostly able to fill the empty capacity slots by demand of other customers. Although cancellations are not formally punished in case 2, the outsourcer is careful with this option to avoid a deterioration of the relationship. On top of that, cancelling too much will probably result in a penalty fee on the long term. Figure 5 shows the (order) decisions that are made by the outsourcer on a time scale.

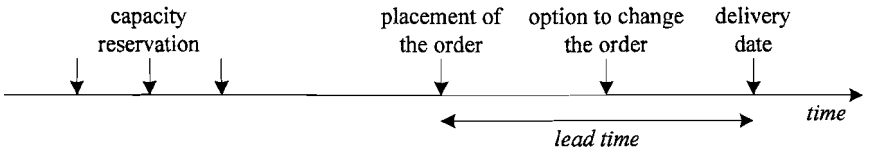

Figure 4. Decisions made by the outsourcer on a time scale

Proposition 5: The order release process towards the contract manufacturer consists of different connected decisions in time. Therefore, releasing orders towards the contract manufacturer requires a more sophisticated (multi-level) decision process. By not doing so, a nervous ordering behaviour results, as the outsourcer reacts to the "arbitrary" behaviour of the contract manufacturer.

Another insight that we got from case study 1, which also complicates the planning of the outsourced operations, is the delay of information from the contract manufacturer. In order to plan his supply chain, the outsourcer also needs inventory data from the contract manufacturer. Case study 1 has shown that the contract manufacturer is not able to provide these data on time, which enforces the outsourcer to *estimate* the inventory levels at the contract manufacturer. The estimation is done by adapting the last information that was provided by the contract manufacturer by receipts or shipments in the previous month(s). This estimate is rather accurate in case of no (quality) rejections. However, quality rejections of complete batches occur quite often, which result in substantial errors of the estimation.

Proposition 6: The planning of outsourced operations gets complicated by delays in and asymmetries of crucial information.

So far, we discussed the insights that we gathered from the case studies based on similarities that we found between the two case studies. However, the contracts between the parties differ completely in the two cases. The contract with the first contract manufacturer, who is located in the United States, contains a lot of agreements and penalty clauses. Agreements are made on the annual volumes, bounds for the change that can be made in the ordered quantities, the logistics performance, cancellation fees, and penalties for not meeting the logistics performance, and bounds for changes in the volumes. It is striking that in the second case, none of these agreements were made with that contract manufacturer, who is located in Germany, whereas the way the parties control their relationship is rather similar. Although it is common known that contracts with and between companies in the United States contain much more agreements, we think that this insight should be further investigated, i.e. whether it is needed to have so many agreements and the effects of setting a lot of agreements on the supply chain performance. This has also been addressed by Jiang and Qureshi (2006), who state that there is a lack of research on the outsourcing contract itself.

Proposition 7: Contracts with more tight clauses and more penalty clauses do not necessarily lead to better logistics performance.

5. Conclusions

In this paper, we have developed a framework that discusses the insights from the literature on outsourcing from two perspectives. The first perspective is whether the paper considers strategic or operational outsourcing decisions. Strategic outsourcing addresses the decision whether to outsource and several kinds of related issues such as the risks associated with outsourcing, the (expected) results of outsourcing, and conditions for successful outsourcing. This stream of papers develops insights that assist a firm's decision to outsource. Outsourcing on the operational level addresses issues that are relevant after having made the outsourcing decision, such as how to manage the outsourcing relationship, how much to outsource, and which orders to outsource. The second perspective is whether the insights from the paper are

developed based on a qualitative study (case study, empirical work) or based on a quantitative study (formal, mathematical modelling).

Two insights have been gathered from the framework, which are expressed in propositions 1 and 2. The first insight is that the literature lacks (qualitative) studies on the effect of outsourcing at the operational level. Outsourcing has mainly been approached from a strategic level, where outsourcing decisions have been studied extensively. The few studies that address operational outsourcing decisions are not based on empirical data. Second, the studies that are conducted at the operational level consider outsourcing as a secondary option in addition to to the internal manufacturing capability, in order to make it possible to achieve certain objectives (to control the customer required lead time, to cover excess demand or to deal with demand uncertainties). These two insights gave rise to performing the two case studies, as there is a need to gather qualitative empirical insights into outsourcing at the operational level, especially in case the contract manufacturer is the only source for supplying the materials to the outsourcer. These case studies give insights that are helpful in incorporating outsourced operations in the outsourcer's supply chain planning model.

We discussed the case studies in section 3 and showed the supply chain structures of the outsourced operations, the contractual and informal agreements and the information flows between the parties. Based on the case studies, we developed a couple of propositions that we explained in section 4. These propositions give some insights into the implications of outsourcing on the operational planning. We showed that an outsourcing relationship is more complex than a simple supplier-buyer relationship. We also showed that the order process towards the contract manufacturers is complicated by the different connected decisions in time. This means that the order process becomes a hierarchical process where a higher decision level constrains the lower decision level. We have seen in the case companies that by ignoring this, a nervous ordering behaviour results, which deteriorates the supply chain performance.

These propositions are meant to shed light on an area that has not yet been documented in the literature and to show the complexity of outsourcing at the operational level. These results seem to be generalizable to at least the pharmaceutical industry, but more research is needed to determine whether the results and insights replicate in industries other than the pharmaceutical industry.

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