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Product Recalls and Supply Chain Responsiveness

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Abstract
The increase in product recalls which occurred in recent years is mainly due to the globalization of the supply chains, in particular the outsourcing and offshoring of manufacturing and distribution. Besides being the main cause of recall, in this paper we argue that outsourcing (domestic and international) and offshoring may also affect the supply chain responsiveness in managing the recall itself. We test a number of hypotheses on this theme empirically on the pharmaceutical sector by using data collected from the American Food and Drug Administration (FDA).

Keywords: Product recall; Supply chain responsiveness; Outsourcing/Offshoring.

Introduction
Although previous studies in product recall investigate the causes of recalls and identify operations globalization as one of the main cause of them (Stevens et al. 2014), in this paper we argue that outsourcing (local and international) and offshoring may also affect the supply chain responsiveness in managing the recall itself. The supply chain responsiveness in managing the recall is meant as the supply chain ability to quickly react and manage the withdrawal of damaged products from the market. In fact, previous studies focus in understanding the factors that influence the time to recall, i.e. the time between the quality failure detection and the product recall announcement (Potter et al., 2014) or the total recall timeline (Hora et al., 2011). However, these kinds of measure do not necessarily take into account the gravity of the recall in terms of the amount of products and lots of them that have to be withdrawn from the market due to the quality failure. In Figure 1 we show the complex timeline of a recall, starting from when the first product of a specific lot is sold, and ends when the firm announces the recall. In this paper we are not considering the time for physical withdrawing the products from the market.

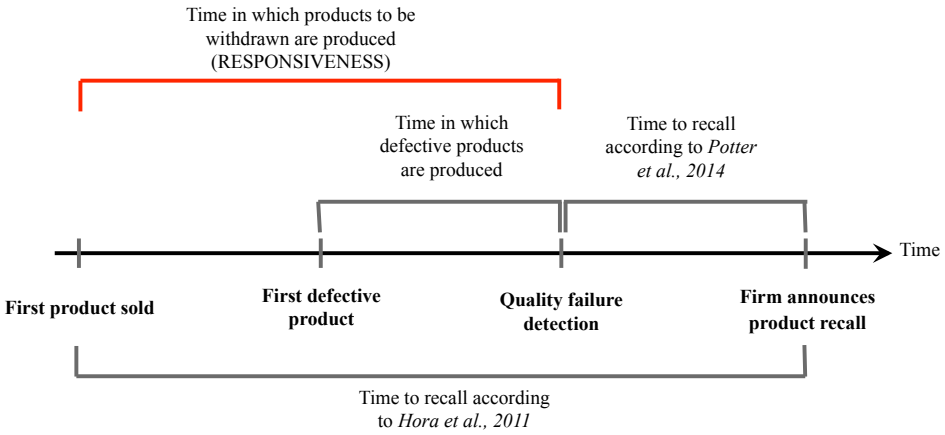


Figure 1 – Recall timeline

We know that the damages caused by recalls are significant in terms of logistics and repairing costs (Jarrell and Peltzman 1985), in terms of stock market negative reaction (Ni et al. 2014), and in terms of social issues (Hora et al. 2011). Thus, the damages coming from the recall are more severe when the number of products to be withdrawn is higher. When looking at the timeline of the recall (Figure 1), it is easy to comprehend that the amount of products to be recalled are those produced in the time window between "when the first product of the lot is sold" and the time when the company detects the quality failure and stops the production. Due to this reasons we argue that the real supply chain responsiveness correspond to this time window (in red colour in Figure 1).

In conclusion, besides developing strategies to reduce the number of recalls, it is of crucial importance to develop supply chain strategies oriented to effectively and timely reduce the damages caused by each recall, for example by limiting the number of lots to be withdrawn (Luo, 2008). This research wishes to contribute to the literature on product recalls along this perspective (Lyles et al., 2008), by investigating how global operations strategies act as antecedents of the responsiveness of the supply chain against product recalls. The results we get can help making decisions about how to configure global operations to minimize damages resulting from product recalls.

We choose to test empirically our hypotheses on the pharmaceutical sector for several reasons. Firstly, in this industry the quality of the product is one of the most important competitive dimensions; off-quality products do not just increase costs and decrease company's reputation, but also they may lead to significant human safety problems. Moreover, many major pharmaceuticals are aggressively adopting global sourcing, outsourcing and offshoring strategies to pursue cost saving in production.

Literature review

In this section we aim to offer a non-exhaustive review of the literature that examines the phenomenon of product recall. We organize the reviewed papers around the following main categories: First authors; Years; Recall area; Industry; Independent variables; Dependent variables. Drawing upon on the literature on product recalls, we have developed our review in accordance with the framework of Bapuji and Etayankara (2009) that divides the literature on product recall into four principal areas: recall causes & prevention (antecedents to product recalls), recall characteristics (i.e. as recall size, recall harm, and

recall trends), recall management (actions of managers in a recall situation), and recall consequences (the effects of recalls). We summarize in Table 1 the literature review results. The main findings of this analysis follow.

Table 1 - Overview of previous literature

First Author	Year	Recall area	Industry	Independent Variables	Dependent Variables
Allen	2008	Characteristics	Toy		
Bapuji	2007	Characteristics	Toy		
Bapuji	2008	Characteristics	Toy		
Bapuji	2009	Characteristics	Toy		
Barney	2008	Causes			
Bates	2007	Characteristics	Automobile	Model offered	Recall rates
Beamish	2008	Causes	Toy	Global sourcing	Reason of recall
Bode	2011	Causes		Information processes	Supply chain responsiveness
Buckley	2007				
Cheah	2007	Consequences	Pharma	CSR	Stock price
Choi	2006			Supply chain complexity	Transaction cost Risk; Responsiveness Innovation
Chu	2005	Consequences		Recall announcement	Stock price
Corbett	2005				
Cummings	2003			Geographical distance; Cultural distance; Norms distance	Knowledge transfer
Dranove	1994	Consequence	Pharma	Recall announcement	Stock price
Galbraith	1990				
Gibson	1995	Consequence		Customers communication	Product recall
Govindaraj	2004	Consequence	Automobile	Recall announcement	Stock price of competitors
Grackin	2008		Pharma	Global sourcing	Risk prevention
Gray	2011	Causes	Pharma	Offshore activity	Quality risk
Haunschild	2004	Causes	Automobile	Recall strategy	Recall severity
Hoffer	1988	Consequence	Automobile	Recall announcement	Stock price
Hora	2011	Consequence	Toy	Recall strategy; Reason of recall; Supply chain entity	Time to recall
Jarrell	1985	Consequence	Pharma Automobile	Recall announcement	Stock price
Kakabadse	2003			Outsourcing	
Kumar	2006	Management	Food	Best practices for recall management	Recall prevention
Luo	2008	Causes		Managers behaviour in the global market	Product recall
Lyles	2008	Causes		Supply chain complexity	Product recall
Marucheck	2011		Food; Pharma; Consumer good Automobile	Global supply chain	Product safety
Ni	2014	Consequence		Private label; Recall strategy; Product hazard	Stock price
Potter	2014	Consequence	Food	Geographical distance	Time to recall
Pruitt	1986	Consequence		Recall announcement	Stock price
Riswadkar	2007	Consequence			
Roth	2008	Management	Food		
Smith	1996	Consequence		Manage recall	
Steven	2014	Causes	Manufacturing	Outsourcing intensity; Offshoring intensity	Number of recalls
Stringfellow	2007			Geographical distance Cultural distance	Indirect cost
Tang	2008	Management	Toy		
Teagarden	2009	Characteristics	Toy		
Teratanavat	2005	Cause	Meat	Resource availability	Time to recall
White	2003	Cause			
Woo	2008		Toy		
Zhao	2013	Consequence	Automobile Food Electronics Pharma	Recall announcement; Recall strategy; Industry	Stock price

The biggest source of problem for product recalls, especially for manufacturing firms, appears to arise from global supply chains, due to the geographical and socio-cultural distances between customer and supplier. For example, Gray et al. (2013) found that in the pharmaceutical industry, offshoring increases quality risk, therefore companies need to adequately monitor and inspect the quality through appropriate strengthening of their contract manufacturing paradigms. Moreover, Steven et al. (2014) found that when companies increase their outsourcing and offshoring activities the number of recall increases too.

Despite the importance of the topic and the interest by scholars, no much has been said in the literature on how companies can quickly react to a product recall. Only few authors have studied the factors that influence the time to recall. For example, Hora et al. (2013) investigated the relationship between the company recall strategies and time to recall (Figure 1), while Potter et al. (2014) have studied how the geographical distance between customer and supplier affect the time to recall (Figure 1).

This literature review reveals two main aspects of the phenomenon. First, global sourcing is one of the most investigated causes of product recalls. Secondly, it is important for a company quickly reacts to a situation of product recall to limit the damage, which implies a responsive supply chain to recall. In the existing literature, however, the relationship between these two factors remains an unexplored area, in our view a better understanding of the impact of outsourcing and offshoring on the responsiveness of the supply chain would give a great contribution to literature and would be of great interest to the managers.

Hypothesis development

The theoretical framework is based upon literature-based argumentation about some relationships between outsourcing/offshoring activities and supply chain responsiveness to recall, but also the reason of recall; we also considered the effect of cost saving as moderator of these relationships. Figure 2 illustrates this conceptual model.

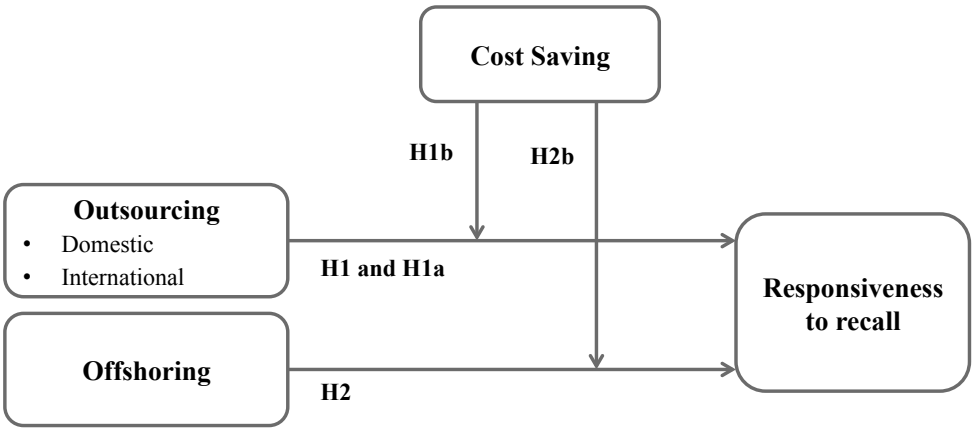


Figure 2 – Conceptual model

Outsourcing decisions involve activities that the firm buys from other firms. The greater complexity of the supply chain, both in terms of the number of partners and their geographical distance, makes it difficult to track and control products and therefore the risk of quality failures increases (Kakabadse and Kakabadse, 2003). Besides having a negative

effect on product quality, we hypothesize that outsourcing also compromises the ability of the supply chain in reacting to the recall. Hora et al. (2011) have shifted research attention from why defective products are recalled towards why it takes firms so long to respond to these events. Potter et al. (2014) have identified that one of the ways to mitigate the impact of a supply chain disruption (e.g. a product recall) is to improve organizational responsiveness. In particular, one of the most effective ways to mitigate the impact of a supply chain disruption is to reduce the supply chain's response time. However, even a short response time could lead to very high costs because a high number of lots of product have to be retired. From this perspective, supply chains differ in the way in which they process and interpret information and respond to a product quality failure.

H1: The supply chain responsiveness in recalling damaged lots of products is lower when their production are outsourced.

It has been already empirically shown that when the outsourcing becomes international the risk of product quality failures increases, thus increasing the number of recalls. This is due to a number of cultural issues that can bring opportunistic behaviours among suppliers. Furthermore, the geographical distance may protect suppliers from being recognized and blamed for quality failures. Therefore, moral hazard may lead to more quality concerns when suppliers are located in foreign countries. This exacerbates the complexity of the supply chain base; the supply chain becomes longer, more complex, less visible, and less traceable when outsourcing is offshored (Choi and Krause, 2006). Consequently, oversight becomes more costly and less effective to respond to a product quality failure.

H1a: The relationship between responsiveness to recall and outsourcing is stronger when the outsourcing is international.

Outsourcing has a direct and an indirect effect on business performance. The direct effect is due to the cost saving, while the indirect effect may be associated with damage caused by product recalls and thus counteracts direct cost saving. The interaction of these two contrasting effects might be the explanation of the inconsistencies of the literature on the relationship between outsourcing and business performance (Steven et al. 2014). In case of global sourcing, risk prevention models should be driven not by cost-based models, but by total-sourcing models, which take into account the costs associated with any disruption of supply and product liability. Thus, we expect that the managers that exploit the low labor costs in emerging countries, will implement policies of relocation to countries far apart geographically and culturally, will do so at the expense of the responsiveness of the supply chain.

H1b: The relationship between responsiveness to recall and international outsourcing is stronger when the outsourcing takes place in countries with low labor costs.

When production is moved offshore, the decisions related to the offshored plant are taken by local agents who, although monitored and evaluated by foreign principals, work semi-

autonomously. This displacement of the decision center may complicate the flow of information and knowledge, because of the geographical and cultural distance between the managers of the parent company and those of offshore plant. Moreover, global sourcing practices (international outsourcing and offshoring) make the exchange of information between the parent company and the production plant more difficult. We can argue that the problem is more pronounced in a situation of international outsourcing than offshoring. In fact, in an offshore environment, the parent company somehow controls the management of the offshore plant, which usually inherits best process, organization, and operational models of the parent company.

H2: The supply chain responsiveness in recalling damaged lots of products is lower when their production are offshored, but greater respect to international outsourcing.

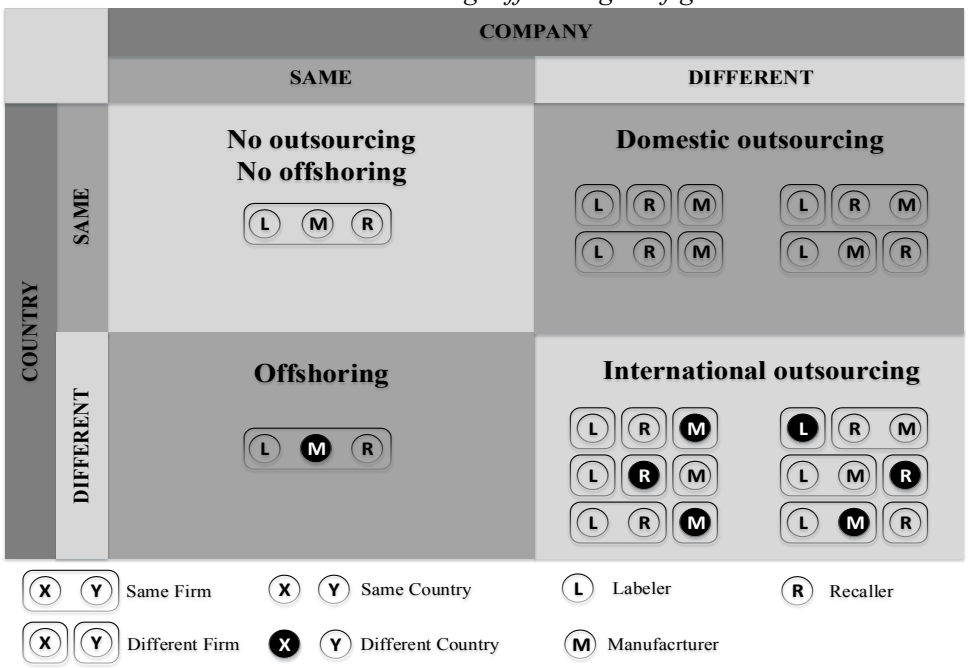
Finally, we hypothesize that the same considerations we did about international outsourcing in low labor cost countries apply for offshoring in low cost countries.

H2a: The relationship between responsiveness to recall and offshoring is stronger when the offshoring takes place in countries with low labor costs.

Research methodology

The empirical setting of this research is the pharmaceutical industry. To perform the analysis we collected data from various sources. The data relating to recall announcements of drugs have been extracted from the website of the FDA from which we collected data on 1009 recalls in the years 2012-2014.

Table 2 – Outsourcing/Offshoring configurations



For each product recall announcement we collected data on the actors of the supply chain involved in the recall, namely the company that owns the drug (*Labeler*), the company that recalls the drug (*Recaller*) and the company who has manufactured the drug (*Manufacturer*). Table 2 shows the different relationships between labeler, manufacturer the recaller related to the company and the country. Also, we collect data on the recall itself, such as the reason underlying it and the number of lots that have been withdrawn. For each recall, the attribute-data of all the actors were taken from the SDC Platinum database, while data on countries' labor cost were taken from the Bureau of Labor Statistics (BLR) database.

The measurement of dependent and independent variables is summarized in Table 3. Finally, we controlled for a number of factors related to recall such as *Units Recalled*; *Product category* (Specific drug, Generic drug, and OTC drug); *Class of risk*, (Class I, II and III); *Products in announcement*. Also we controlled for the *Area of the recall* (Manufacturing, Distribution, and Storage). Finally, we control for a number of factors related to the firm, such as *Industry* (Pharmaceutical, Biotechnology and Distribution); *Firm size*; *Marketed product*; *Firm age*; and *Country*.

Table 3 – Variable names and measurements

Variables	**Measurements**
Dependent variables	
Number of lots	The number of lots involved in each recall.
Independent variables	
Outsourcing	Takes value 0 if the manufacturer and the recaller are the same company of the labeler; 1 if the manufacturer and/or the recaller is a different company than the labeler.
Domestic outsourcing	Takes value 1 if *Outsourcing* is 1 and the three companies are located in the same Country; 0 otherwise.
International outsourcing	Takes value 1 if *Outsourcing* is 1 and at least one of the three supply chain actors is located in a different Country respect to that in which the labeler is registered; 0 otherwise.
Offshoring	Takes value 1 if the labeler, the recaller and the manufacturer are the same company and the manufacturing plant is located in a different Country of the registered office of the labeler; 0 otherwise.
Cost saving	The difference of the hourly labor cost in the Country of the labeler and the hourly labor cost in the Country where the production is outsourced/offshored.

Results

Because of the discrete nature of the first dependent variable *Number of lots* we applied a negative binomial regression (Table 4). In Model 2 the coefficient of *Outsourcing* is positive and significant, providing support to the first hypothesis.

Table 4 – Negative binomial regression

	Number of Lots						
	Model 1	Model 2	Model 3	Model 4	Model 5	Model 6	Model 7
Unit recalled	0.394***	0.391***	0.394***	0.395***	0.393***	0.394***	0.394***
	(0.0151)	(0.0150)	(0.0150)	(0.0150)	(0.0150)	(0.0150)	(0.0150)
Generic	-0.0315	-0.0460	-0.0570	-0.0254	-0.0522	-0.0609	-0.0299
	(0.0746)	(0.0739)	(0.0734)	(0.0745)	(0.0748)	(0.0736)	(0.0749)
OTC	-0.0563	-0.0534	-0.0743	0.0223	-0.0383	-0.0672	0.0354
	(0.0989)	(0.0982)	(0.0973)	(0.102)	(0.0987)	(0.0978)	(0.102)
Manufacturing	-0.0508	-0.0154	-0.0400	-0.0916	-0.0532	-0.0404	-0.0813
	(0.0922)	(0.0915)	(0.0906)	(0.0928)	(0.0919)	(0.0906)	(0.0925)
Storage	-0.101	-0.0600	-0.114	-0.0791	-0.0755	-0.109	-0.0806
	(0.120)	(0.119)	(0.119)	(0.120)	(0.120)	(0.119)	(0.120)
Class of risk	0.191**	0.187**	0.187**	0.172**	0.199***	0.189**	0.180**
	(0.0587)	(0.0582)	(0.0579)	(0.0587)	(0.0584)	(0.0580)	(0.0589)
Products_anns	0.00395	0.00242	0.0000442	0.00491	0.00515	0.000327	0.00442
	(0.00386)	(0.00384)	(0.00395)	(0.00392)	(0.00388)	(0.00397)	(0.00389)
Pharma	0.146	0.177	0.192	0.157	0.146	0.191	0.153
	(0.157)	(0.155)	(0.155)	(0.156)	(0.156)	(0.155)	(0.156)
Distribution	0.374+	0.251	0.257	0.323	0.326	0.251	0.321
	(0.202)	(0.202)	(0.201)	(0.202)	(0.203)	(0.201)	(0.202)
Size	-0.134***	-0.109***	-0.106***	-0.122***	-0.123***	-0.104***	-0.121***
	(0.0157)	(0.0162)	(0.0159)	(0.0159)	(0.0161)	(0.0161)	(0.0162)
Mkt_product	0.00123***	0.00126***	0.00130***	0.00128***	0.00128***	0.00131***	0.00128***
	(0.000114)	(0.000113)	(0.000112)	(0.000116)	(0.000116)	(0.000113)	(0.000116)
Age	0.00203*	0.00113	0.00136+	0.00171*	0.00181*	0.00134+	0.00180*
	(0.000803)	(0.000804)	(0.000788)	(0.000803)	(0.000803)	(0.000788)	(0.000803)
Country	-0.405***	-0.375***	-0.389***	-0.330***	-0.455***	-0.408***	-0.414***
	(0.0786)	(0.0778)	(0.0816)	(0.0851)	(0.0810)	(0.0869)	(0.0819)
Outsourcing		0.349***					
		(0.0698)					
Domestic			0.459***			0.447***	
			(0.0778)			(0.0800)	
International			0.194*	0.195*		0.172*	
			(0.0777)	(0.0801)		(0.0850)	
Cost saving				-0.00964***			-0.00231
				(0.00266)			(0.00246)
IntOutXCost saving				0.0591*			
				(0.0272)			
Offshoring					-0.268**	-0.0699	-0.172+
					(0.0969)	(0.106)	(0.104)
Off X Cost saving							-0.0617*
							(0.0246)
N	1009	1009	1009	1009	1009	1009	1009
LR chi^2	702.89	727.69	742.73	720.68	710.43	743.16	720.17
Log likelihood	-2545.79	-2533.39	-2525.87	-2536.89	-2542.02	-2525.65	-2537.14

Standard errors in parentheses and + $p < 0.10$, * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

In model 3 outsourcing is split into *domestic* and *international outsourcing*; both the variables are significant and positive, but unlike what we expected the difference among coefficients does not provide evidence that the number of lots recalled is significantly worse when outsourcing is international respect to the domestic one. Hence, the hypothesis *H1a* cannot be accepted. The interaction coefficient between *international outsourcing* and *cost saving* is significant and positive (Model 4); this confirms the hypothesis *H1b*. *Offshoring* coefficient has a significant and negative effect on the number of lots to be withdrawn (Model 5), so H2 is not supported. Finally, the coefficient of the interaction between *offshoring* and *cost saving* is significant and negative (Model 7) so the hypothesis H2a is rejected.

Discussion and conclusion

The main contribution of this work comes out from the finding that outsourcing and offshoring have a different and opposed effect on the responsiveness of the supply chain in recalling products. In fact, we have seen how outsourcing makes the supply chain more complex and thus less responsive, while offshoring strategies improve the responsiveness of the supply chain. We can say, then, that it is not the internationalization itself to determine lacks of responsiveness, but this is caused by outsourcing practices (either domestic or international). This finding is made even stronger by the comparison we made between domestic and international outsourcing, which brought to the conclusion that the internationalization of outsourcing does not lead to more significant deterioration of responsiveness than domestic outsourcing. This gives us further confirmation that internationalization is not the source of the problem.

The second contribution is the result we obtain on the effect that the reduction of operational costs achieved thanks to global sourcing has on responsiveness. In line with what we expected, when the outsourcing is international the rise of cost saving decreases responsiveness. Conversely, when internationalization is done through offshoring lower operational costs improve responsiveness. The results, although innovative, seem to be in line with previous studies. In fact, a possible explanation for the different effects of outsourcing and offshoring on supply chain responsiveness may be that thanks to offshoring the company achieves both the reduction of information asymmetry and the absence of opportunistic behavior in contrast to what happens in the buyer-supplier relationship typical of outsourcing. Also when, in order to pursue big cost savings, the offshored product plants are located in countries geographically and culturally far apart, it is plausible to think that managers are aware of the risk of information asymmetry and put in place best practices to foster communication and alleviate asymmetry, all this will benefit supply chain responsiveness.

Our study has also important managerial implications. Firstly, when sourcing is globalized the main problem related to the responsiveness of the supply chain can be attributed to the outsourcing practice. Thus, managers should take this important finding into consideration in defining and planning global sourcing strategies for the reduction of production costs. Moreover, the findings reveal that the effectiveness of the offshoring is closely related to the information and knowledge exchanged between parent company and plant production, and the level of trust established between these two actors. For this reason, when implementing practices of offshoring managers have to pay attention to the international communication systems and the exchange of knowledge.

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