Lean Readiness – The Case of the European Pharmaceutical Manufacturing Industry

Purpose – The purpose of this paper is to assess the quality practices of European pharmaceutical manufacturers to determine the level of readiness of this industrial sector to implement and/or sustain lean manufacturing (LM).
Design/Methodology/Approach – An assessment framework developed by Al-Najem *et al.* (2013) was adapted to evaluate how ready European pharmaceutical manufacturers are to implement and/or sustain lean manufacturing. Therefore, the lean readiness (LR) level of these organisations was assessed through six quality practices related to LM. These included: processes; planning and control; human resources; top management and leadership; customer relations; and supplier relations. One research question and three hypotheses were formulated and tested using a combination of descriptive statistics and non-parametric Mann-Whitney tests. Data was collected through a survey questionnaire distributed to 310 European pharmaceutical manufacturers and responded by 37 of these organisations.
Findings – Overall, the results of this study indicate an inadequate level of LR for the participating firms. Simultaneously, it was concluded that factors such as company size, type of relationships with suppliers and ISO 9000 certification do not have an effect on the quality practices, and hence LR level, of European pharmaceutical manufacturing organisations.
Practical Implications – This study provides crucial information regarding the LR level of European pharmaceutical manufacturers, which can now be aware of the areas in their practices that require further improvement towards a successful lean journey. Simultaneously, organisations in the pharmaceutical sector that intend to implement LM can consider the results of this study and evaluate their readiness level**.** Managers can therefore refer to this research and use it as a platform to take better decisions regarding what quality aspects of their operations need to be enhanced to successfully deploy or sustain a lean strategy.
Originality/Value – This research is one of the very few studies that have focused on evaluating whether the European pharmaceutical manufacturing industry is ready to successfully implement or sustain LM. Therefore, this research expands the limited existent body of knowledge of LM in this industry.

Keywords: European Pharmaceutical Manufacturing Industry; Lean Manufacturing; Lean Readiness; Quality Practices.

Paper type: Research paper

1. Introduction

Over the past two decades, both manufacturing and service industries have been severely affected by new technological opportunities and challenges, which have set new levels for global, regional, and local competition (Chowdary and George, 2011). As a consequence, the enormous pressure from competitors and customers, in terms of delivering greater value for products and services (Kumar *et al.*, 2006), has prompted manufacturing firms to turn to operational excellence initiatives in order to improve the quality of their products and services while simultaneously reducing manufacturing costs and cycle times (Belekoukias *et al.*, 2014; Arya and Jain, 2014). According to Bonavia and Marin (2006) and Garza-Reyes *et al.* (2012), one of the best systems to move towards this direction is lean manufacturing (LM).

Following the success of Toyota, numerous manufacturing and service organisations across different industries, geographical territories and sizes have applied LM practices with the aim of improving efficiency and productivity (Dora *et al.*, 2013a). However, despite the reported tangible and intangible benefits that Toyota and other Japanese automotive manufacturers have experienced in their operational environments (Serrano Lasa *et al.*, 2009), few organisations around the world have achieved considerable improvements from their lean efforts (Arya and Choudhary, 2015). For instance, Bhasin (2012) and Bhasin and Burcher (2006) concluded that less than 10% of the companies that pursued LM reported an overall and conclusive success. Many reasons are believed to lie behind this phenomenon, from which one of the most important is the lack of complete understanding of lean concepts and general purpose (Mostafa *et al.*, 2013). Simultaneously, Dora *et al.* (2013a) asserted that academic studies revealed divergent results of lean systems adoption in different industries and sectors, while Dora *et al.* (2013a) also emphasised the need for conducting more industry-centred studies in order to determine whether the lean theory applies to all manufacturing and service sectors. In response to this statement, this study focuses on a specific sector of the pharmaceutical industry, namely: European pharmaceutical manufacturers.

Various authors have accentuated that the pharmaceutical industry has been slower than other industries in embracing the lean theory (O'Rourke and Greene, 2006; Wagner *et al.*, 2009; Pavlović and Božanić, 2012; Selko, 2011). Reasons behind this fact involve the relatively small cost of goods compared to the companies' cost structure (Selko, 2011) as well as the strict quality standards that characterise the pharmaceutical industry (Chowdary and George, 2011). Similarly as with the overall pharmaceutical industry, European pharmaceutical manufactures remained inert to the lean wave until the start of the 21st century, when big European pharmaceuticals such as Novartis, AstraZeneca and GSK initiated their lean journeys (Chatterjee, 2014). The European pharmaceutical industry is considered a valuable asset of the European economy, with the best performing ratio among all other industries in the continent, and with a 25 percent value of the overall global pharmaceutical industry (Nenni *et al.*, 2014). However, this industry has been facing important challenges related to the increase of R&D costs, decline in efficiency, expiration of numerous patents (Nenni *et al.*, 2014), which has resulted is a considerable drop in profits (Friedli *et al.*, 2013). As a result, an imperative need for improving their operational performance through the adoption of process excellence programmes such as the lean approach has emerged as an opportunity to address these challenges (Wagner *et al.*, 2009; Friedli *et al.*, 2013).

However, despite some evidence of the application of lean manufacturing in the pharmaceutical industry exists, and especially in companies such as Lundbeck, GSK and Novartis (Friedli *et al.*, 2013; O'Rourke and Greene, 2006; Chowdary and George, 2011), there is still no consensus in the academic literature regarding the applicability of lean initiatives in the European pharmaceutical sector, and the capability of the latter to support lean initiatives.

In addition, besides the reported cases of LM implementation in the pharmaceutical industry, there is no study in the academic literature that focuses on the exploration of the lean readiness (LR) level of European pharmaceutical manufacturers. In this line, Al-Najem *et al.* (2013), Garza-Reyes *et al.* (2015) and Anand and Kodali (2008) have highlighted the lack of exploratory studies regarding the LR level of other industries, besides the automotive where LM was born. Therefore, and considering the importance of the European pharmaceutical industry, this paper investigates the level of readiness of this industrial sector to provide a good foundation for the implementation or sustainment of the lean manufacturing.

Lean practices have been assessed through various frameworks proposed in the academic literature (Panizzolo, 1998; Mady, 2009; Furlan *et al.*, 2011; Shah and Ward, 2003; Nordin *et al.*, 2010; Gupta *et al.*, 2013; Anand and Kodali, 2009). However, Al-Najem *et al.*'s (2013) framework was selected as the most appropriate for this study due to it evaluates lean readiness (LR) based on quality practices that are considered enablers of LM (i.e. processes; planning and control; human resources; top management and leadership; customer relations; and supplier relations). For this reason, besides providing an insight into the LR of the European manufacturers, it also provides understanding regarding its quality practices.

2. Literature review – formulation of research question and hypotheses

Extensive evidence suggests LM as an effective approach to aid organisation in being more competitive through the achievement of excellence in their operations (Belekoukias *et al.*, 2014; Arya and Jain, 2014). However, factors contributing to the failure in the deployment and sustainment of lean practices have resulted in a large number of cases being reported in the academic literature where lean benefits have not been realised (Arya and Choudhary, 2015; Bhasin and Burcher, 2006). For this reason, there is a need to assess the practices of organisations to determine whether these are supportive of the implementation or sustainment of LM, or if they need to be enhanced or adapted to support and facilitate the lean philosophy. In this line, organisations need to evaluate their preparedness (i.e. readiness) to support LM (Al-Najem *et al.*, 2013). This led to the formulation of the following research question:

RQ1. Are European pharmaceutical manufacturers capable of supporting lean manufacturing practices?

Furlan *et al.* (2011), Shah and Ward (2003), Dahlgaard and Dahlgaard (2001), Cua *et al.* (2001) and Andersson *et al.* (2006) suggest that existing quality practices play a significant role in succeeding in the implementation and sustainment of LM. For example, Furlan *et al.* (2011) comment that quality practices can both continue supporting LM after it has been implemented and aid in its initial deployment. Al-Najem *et al.*'s (2013) assessment framework was developed based on this relationship between quality practices and LM. Therefore, the aim of this paper is not to assess the leanness (Belekoukias *et al.*, 2014) of European pharmaceutical manufacturers, but to evaluate their quality practices to determine whether these organisations have the capabilities to implement or sustain LM. Al-Najem *et al.* (2013) justifies six cultural and technical constructs and requirements for LM, which equally have a relationship with quality practices. These include the whole chain of LM, moving through suppliers, internal processes and customers (Al-Najem *et al.*, 2013). The constructs include: processes; planning and control; human resources; top management and leadership; customer relations; and supplier relations.

2.1 Lean manufacturing in Small and Medium Size Enterprises (SMEs)

Following Toyota's success, countless firms around the world and across different sectors, regions and sizes imitated its lean system in their effort to achieve similar levels of performance

(Dora *et al.*, 2013b). However, it is evident that most of the scholarly articles on the LM literature are dedicated to its implementation in large organisations (Al-Najem *et al.*, 2013). In response, recent publications have addressed the issue of LM applicability and suitability in the extent of SMEs (e.g. Saad *et al*., 2006; Dora *et al.*, 2013b; Rose *et al.,* 2011; Second, 2010).

The importance of SMEs globally, and in the European context, has been extensively highlighted over the past decade. More specifically, according to Saad *et al.* (2006), SMEs constitute a vital part of the manufacturing industry and simultaneously a driving force for the sustainability of national economies. Similarly, Bakas *et al.* (2011) also stressed the pivotal role of SMEs in the European economy, where those companies employ a huge percentage of the entire workforce and contribute considerably to the creation of value for customers. As far as the pharmaceutical sector is concerned, the European pharmaceutical industry consists of 1301 registered SMEs, where the majority focuses on drug development (EMA, 2014). In this regard, the introduction of LM in SMEs constitutes an issue of major importance in the pursuit of achieving higher productivity in the sector.

When the literature is reviewed, it can be comprehended that the issue of LM applicability in SMEs remains questionable (Anand and Kodali, 2008; Dora *et al*., 2013b). On one hand, some authors have raised concerns over the direct adoption of LM practices in SMEs. In more detail, a number of factors including the lack of financial resources and strong leadership as well as the nature of the relationship with customers and suppliers hinder the lean journey of SMEs (Rose *et al*., 2011; Saad *et al*., 2006; Achanga *et al*., 2005). Similarly, the results of the researches conducted by White *et al.* (1999) and Golicic and Medland (2007) accentuated the enormous difficulties that implementing and sustaining LM imposes to SMEs.

However, some researches from Cua *et al.* (2001), Bonavia and Marin (2006) and Mallur *et al*. (2012), by examining the effect of company size when implementing lean in the area of Karnataka and the Spanish tile ceramic industry, concluded that large organisations and SMEs do not differ in their capability to adopt quality practices such as TQM and LM (Al-Najem *et al.*, 2013). This observation is further supported by the studies of Karlsson and Åhlström (1997) and Ghobadian and Gallear (1997), which did not find any effect of the size factor on the capability of applying lean. Therefore, the existing literature does not provide a clear understanding regarding the effect of company size on the successful implementation of lean practices. This, in conjunction with the absence of any evidence within the context of European pharmaceuticals, allowed us to formulate the following hypothesis:

H1: Small and medium-sized firms (SMEs) and large organisations differ significantly with regard to their quality practices in the European pharmaceutical manufacturing industry

2.2 Relationship with suppliers

The role of suppliers is critical in the implementation and sustainment of LM (Al-Najem *et al.*, 2013). Womack *et al.* (2007) were the first that indicated the significance of buyer-supplier relationship in the context of LM, whereas numerous others followed (Doolen and Hacker, 2005). In this regard, Liker (2004) and Baker (2004) alleged that lean implementation must be diffused throughout the whole supply chain in the form of strong suppliers' involvement (Bhasin and Burcher, 2006). Furthermore, Panizzolo (1998), by examining the results of lean implementation in 27 manufacturers, indicated that long-term relationships with suppliers in the form of partnership relations contribute to a more effective lean application process. This view can be supported by the long-established supplier contracts adopted by Toyota in order to achieve just-in-time (JIT) delivery (Smith and Greenwood, 1998). Other authors who have insisted on the imperative need of establishing long-term relationships with suppliers to enable

the implementation of LM include Liker and Meier (2006), Chun Wu (2003) and Liker and Choi (2004).

On the other hand, the opposing view involves the risk of paying non-competitive prices that the buyer faces as well as the risk of reducing the efficiency of the relationship due to the dependency that is created (Panizzolo, 1998). In this regard, Friedli *et al.* (2010) provided evidence that the establishment of long term relationships with suppliers for the sake of some pharmaceutical companies which implemented JIT processes did not bring the expected results. Friedli *et al.* (2010), however, recognise that suppliers serve a critical role in the pharmaceutical industry and its pursuit for increase in process quality.

These contradictory views do not present enough evidence as to whether long-term relationships with supplier can serve as a basis for continuous improvement initiatives such as lean manufacturing. Hence, in order to contribute to the literature by examining the effect of supplier relationships in the case of LM in the European pharmaceutical manufacturing industry, the second hypothesis was formulated as follows:

H2: There is a significant difference in the quality practices used by European pharmaceutical manufacturing firms with long-term supplier relationships compared to those with short-term relationships established

2.3 ISO contribution to lean manufacturing implementation

Various factors have been identified to contribute in the pursuit of achieving and sustaining competitive advantage for organisations. According to the academic literature, one of those factors is the ISO 9000 quality standards (Magd, 2006). In this regard, ISO 9000 is considered a valuable step towards continuous improvement initiatives such as TQM and LM (Al-Najem *et al.*, 2013; Karthi *et al.*, 2011; Gotzamani and Tsiotras, 2001; Sadiq Sohail and Boon Hoong, 2003; Idris *et al.*, 1996; Magd, 2006). Indeed Magd (2006) alleged that ISO 9000 certification can serve as a way to achieve continuous improvement, and as a result LM. However, there is no consensus in the existing literature regarding the degree to which those quality standards will contribute to a long-term quality assurance and a successful implementation of continuous improvement initiatives (Gotzamani and Tsiotras, 2001).

On the one hand, various studies have ascertained the involvement of ISO 9000 towards the implementation of LM and Six Sigma (e.g. Kumar and Antony, 2008; Al-Najem *et al.*, 2013). For example, some studies have suggested that ISO 9000 serves as a basis or supplement to the implementation of TQM (e.g. Gotzamani and Tsiotras, 2001; Magd, 2006; Escanciano *et al.*, 2001). However, an opposite view is suggested by Sun (2000), who comments that ISO 9000 offers a limited platform to support the implementation of TQM and LM. As far as the pharmaceutical sector is concerned, a relatively low level of ISO 9000 certification has been observed when compared to other industries (Freitas, 2009). This is also confirmed by the survey conducted by Corbett and Luca (2002), who reported that only a small percentage of pharmaceutical firms apply ISO 9000 in France and Sweden. However, it must be highlighted that no study in the literature was found to investigate the effect of ISO 9000 towards continuous improvement methods such as TQM or LM in the pharmaceutical industry. For all this, it can be concluded that there is not enough evidence in the academic literature regarding the effect of ISO 9000 on the implementation of LM in pharmaceutical manufacturing firms. As a result, the previous premises can be applied in the context of European pharmaceuticals, where quality assurance constitutes a critical success factor. Hence, a third hypothesis has been formulated as follows:

H3: ISO 9000 certified pharmaceutical firms differ significantly with non-ISO 9000 pharmaceutical firms in Europe regarding their quality practices

3. Research methodology

3.1 Survey questionnaire

Since this study was concerned with the exploration and further understanding of a particular phenomenon (i.e. how ready the European pharmaceutical manufacturing sector is to support the implementation and/or sustainment of LM), the selection of an appropriate data collection method was vital to produce reliable evidence and obtain valid and solid conclusions (Houser, 2008). In this case, since the subject focus was to evaluate the LR, through quality practices, of geographically dispersed pharmaceutical manufacturers in Europe, a survey questionnaire was selected as the most effective source of primary data for this research (Saunders *et al.*, 2012).

The questionnaire was created using the Qualtrics software, which respondents could easily access via mobile devices or web browsers. Easy storage, classification, and analysis of the data collected were achieved through a Qualtrics function which allowed the direct tabulation of the data into Excel spreadsheets. The questionnaire was adapted from that used by Al-Najem *et al.* (2013) and Garza-Reyes *et al.* (2015) in their studies. It was structured in two main parts, consisting of a total of 56 questions. The first part comprised 9 closed questions, which involved both employee and company environment-related questions, the majority of which were designed to test the three developed hypotheses. In particular, Section 1 included questions related to, among other aspects, role and years of experience of the respondent, company's size, application of ISO 9000, implementation of lean, etc. Section 2 consisted of a total of 47 questions, which were divided according to the six constructs (i.e. processes; planning and control; human resources; top management and leadership; customer relations; and supplier relations) of quality practices related to LM as defined by Al-Najem *et al.* (2013). The questions collected both opinion and behavioural data in the form of rating type of closed questions. Behavioural questions were related to what the organisation was doing (e.g. how it was operating in relation to such quality practices), whereas opinion questions were related to the feelings of the respondents towards the quality practices of their companies. To achieve valid and reliable quantitative results, a five-item Likert scale was used for all the 47 questions included in the six constructs. An overview of the specific questions formulated in Section 2 of the questionnaire is shown in Table 1.

Insert Table 1 in here

3.2 Questionnaire reliability and validity

According to Cooper and Schindler (2013) and Crowther and Lancaster (2008), there are two major criteria that must be satisfied for any measurement tool to ensure credible results, namely: validity and reliability. On one hand, reliability refers to the consistent collection of the data (Saunders *et al.*, 2012), while validity is concerned with the extent to which the used data collection method measures what it is supposed to measure (Lancaster, 2008). In order to

mitigate reliability threats (i.e. subject error, participants bias, observer error, observer bias) (Robson, 2002; Saunders *et al.*, 2012) and simultaneously reassure the reliability and validity of the questionnaire, Saunders *et al.* (2012) suggest the conduction of a pilot study. However, since the second part of the questionnaire was adapted from Al-Najem *et al.* (2013) and Garza-Reyes *et al.* (2015), there was no need for a pilot study to be performed. Nevertheless, the questionnaire was sent to four academics, who provided valuable feedback for the improvement of the questions in terms of clarity and comprehensibility. This feedback was used in order to reassure the clarity of the questions as well verify the examination of the three hypotheses through the questions of the first part of the questionnaire.

3.3 Questionnaire distribution and response rate

The respondents were identified and randomly selected from data bases and directories such as Amadeus, IQS Directory, Ezilon and Global Sources. From these sources, 62 widely known pharmaceutical manufacturing firms were identified. Those firms operate in numerous countries in Europe, automatically creating a number of more than 500 possible respondents. However, considering the fact that some of the firms operate only in one or two European countries, the questionnaire was sent to an average of 10 different countries. This reduced the number of possible respondents to 310 firms. Initially, the questionnaire was sent via electronic mail, which resulted in a disappointingly low response rate. Hence, a different approach via LinkedIn was used in order to get contact with the appropriate employees of the selected firms.

Out of the 310 firms, 37 of them with operations is the UK, Switzerland, Italy, Germany, France, Belgium and Denmark completed the questionnaire, resulting in a response rate of 11 percent. Although both sample size and response rate may be considered relatively small, they are still comparable to other similar studies in the field (e.g. Garza-Reyes *et al.*, 2015; Devpura *et al.*, 2014; Antony and Desai, 2009; Antony *et al.*, 2007; Dolen and Hacker, 2005). While the sample is obviously not representative of all the European pharmaceutical manufacturers, the responses provided sufficient data to perform a general exploratory and statistical analysis to obtain some overall conclusions regarding the LR level of manufacturers operating in the European pharmaceutical industry.

4. Results of the study

4.1 Profile of organisations and respondents

Figure 1 illustrates a detail profile of the European pharmaceutical manufacturing organisations that participated in the study. The profile data collected included: position of the individual respondent and his/her years of experience, number of employees and size of his/her organisation, whether the company was ISO 9000 certified and had implemented LM as well as whether it had a short or long relationship with its suppliers. In terms of the LM implementation, if the respondents considered that their organisations had deployed all the lean tools that were suitable for their companies, then this was categorised as a "complete" implementation, otherwise it was considered as an "incomplete" implementation.

Insert Figure 1 in here

4.2 Research question results

RQ1. Are European pharmaceutical manufacturers capable of supporting lean manufacturing practices?

Based on the framework proposed by Al-Najem *et al.* (2013), a calculation of the mean scores from the five-item Likert scale was carried out, using SPSS V.23, for each of the LM-related constructs (i.e. processes, planning and control, human resources, top management and leadership, customer relations and supplier relations). The results are presented in Table 2.

Insert Table 2 in here

According to Al-Najem *et al.* (2013) and Nordin *et al.* (2010), a mean score of ≥ 4.00 is used as a benchmark for the segregation of capable and not capable firms when supporting the implementation and/or sustainment of LM initiatives. This score was adopted from the previous authors' researches within the context of Kuwaiti SMEs and Malaysian automotive firms respectively (Al-Najem *et al.*, 2013). Garza-Reyes *et al.* (2015) also adopted this approach and score in their study of the Turkish automotive suppliers industry. Thus, for the purpose of this paper, a score of ≥4 was considered as the minimum limit to indicate that the European pharmaceutical manufacturers surveyed were LM ready.

As shown by Table 2, the mean scores for the six constructs were lower than 4, indicating a low level of readiness to support LM initiatives. Overall, the European pharmaceutical manufacturing industry appears with an average mean score below 3.70 for all the constructs, which is considerably lower than the minimum required level (Al-Najem *et al.*, 2013; Nordin *et al.*, 2010). In particular, the highest score of 3.92 is found in the category of processes, indicating that European pharmaceutical manufacturers require minor development in this area to support LM. However, these organisations require further development in all the other investigated constructs (i.e. human resources, customer relations, planning and control, top management and leadership supplier relations) as similar scores were observed below 3.7 in all of these.

4.3 Hypotheses results

In this section, the data collected from both parts of the questionnaire was analysed through the use of descriptive and inferential statistics to test the hypotheses previously formulated. In this regard, descriptive tests and non-parametric Mann-Whitney (de Winter and Dou, 2010) tests were conducted, at a significance level of 5% (α-level = 0.05), for each hypothesis. This was done in order to compare the means of the independent groups and determine whether there was any significant difference among them.

H1: Small and medium-sized firms (SMEs) and large organisations differ significantly with regard to their quality practices in the European pharmaceutical manufacturing industry

As it was shown in Section 4.1, 70 percent (26) of the surveyed organisations were large while 30 percent (11) were SMEs. The group statistics of those firms consisting of mean scores, standard deviations and standard error means are presented in Table 3.

Insert Table 3 in here

Considering the mean scores of SMEs and large organisations, it can be seen that SMEs appeared to be more supportive of LM than large firms. In fact, in the processes category, SMEs scored a value of 4.06, higher than the minimum value of 4.0, implying a high level of LR. The results in the other constructs are similar as the scores of SMEs are slightly higher than the scores of large firms, a fact that contradicts the assumption of *H1*. The construct of planning and control is the only one that deviates from the pattern that is identified in the other categories, as large firms appeared to be more developed in their practices in this filed, with a score of 3.67 compared to the 3.44 of SMEs. Following to this analysis, a Mann-Whitney test was conducted to determine whether there was a significant difference in the quality practices of SMEs and large companies of the European pharmaceutical manufacturing industry. Null (*H0*) and alternative (*H1*) hypotheses were formulated regarding the absence of a significant difference (*H0*), or the existence of a significant difference between the two (*H1*). The results of the Mann-Whitney test are shown in Table 4.

Insert Table 4 in here

Table 4 shows that the variances can be assumed equal in all constructs as the significance (2-tailed) level of the Mann-Whitney test (*p*-value) was > 0.05. As a result, *H0* cannot be rejected for any of the constructs. Furthermore, as it can be seen in Table 4, and more specifically the column of Significance (two-tailed), the results from the test statistics also reveal that *H0* cannot be rejected, as the *p*-value is significantly higher than 0.05 in all categories. Consequently, the results indicate that there is not a significant difference between SMEs and large companies in regards to their readiness level towards LM. In other words, the results of the analysis suggest that a company's size does not have any effect on the level of LR. However, it must be highlighted that SMEs appear to be even more supportive of LM as it is shown by their mean scores.

H2: There is a significant difference in the quality practices used by European pharmaceutical manufacturing firms with long-term supplier relationships compared to those with short-term relationships established

Similarly as with *H1*, descriptive data (i.e. mean scores, standard deviations and standard error means) was calculated for the two groups studied. Descriptive statistics and Mann-Whitney tests were also conducted to investigate whether there was a significant difference, in terms of quality practices, between European pharmaceutical manufacturing firms that had long-term relations with their suppliers and those that had short-term relations. Thus, this hypothesis aimed at exploring the effect that supplier relations may have on the adoption or development of quality practices, and hence the LR level of organisations. The results are presented in Tables 5 and 6.

Insert Table 5 in here

Insert Table 6 in here

As it can be observed from the column of mean scores in Table 5, the results vary regarding the capability of the two examined groups to support lean initiatives. To be more specific, in the constructs of processes and supplier relations, 31 out of the 37 participating organisations with long-term established relationships with their suppliers, were found to be more developed and capable of implementing or sustaining LM, but with mean scores lower than the critical value of 4.0. On the other hand, 6 companies with short-term supplier relations were found to have better practices in the fields of planning and control, customer relations, human resources and top management and leadership. Indeed, the highest difference is observed in the factor of top management and leadership, where the European pharmaceutical manufacturers with short-term relationships scored a value of 3.80, compared to 3.51 of the opposite group. In total, by only considering the mean scores of Table 5, all of which range between 3.46 and 3.96, these do not differ significantly for the compared groups of firms, indicating similar practices towards LM.

For the Mann-Whitney test, a null hypothesis (*H0*) regarding a lack of difference in the LR level between firms with long and short-term relations with their suppliers was established. Accordingly, an alternative hypothesis (*H1*) that inferred a difference between these two groups was also formulated. The Mann-Whitney test, see Table 6, showed that the *p*-values for all constructs are higher than the significance level of 0.05, and as a result all variances can be assumed equal for all the categories. In other words, the null hypothesis (*H0*) cannot be rejected for any of the examined constructs. In terms of the test statistics, the results are similar to those obtained for *H1*, revealing considerably greater *p*-values (Sig. two-tailed) than the significance level of 0.05. Consequently, it can be confirmed that there is not a significant difference between the two groups in their practices. For this reason, the null hypothesis (*H0*) was accepted while the formulated main hypothesis from literature review *H2* was rejected. This indicates that the nature of supplier relations does not have an effect on the LR level of European pharmaceutical manufacturers.

H3: ISO 9000 certified pharmaceutical firms differ significantly with non-ISO 9000 pharmaceutical firms in Europe regarding their quality practices

From the respondent companies, 20 were ISO 9000 certified while the rest (17) were not. However, since 3 of the 20 ISO certified firms had adopted lean first, and then obtained the ISO 9000 certification, these three companies were excluded from the analysis. Group statistics, for the two groups of 17 companies, including mean scores, standard deviations and standard error means were calculated. The results are presented in Table 7. As can be seen form this table, apart from the processes construct, where ISO certified firms prevailed over the non-ISO certified firms with a mean score of almost 3.93 and 3.92 respectively, in all other constructs non-ISO organisations were found to be more supportive towards LM. However, as the mean scores were almost identical within the two groups, no evidence can be provided to conclude that ISO 9000 certified organisations differ from non-ISO 9000 companies in their quality practices, and hence LR level. To statistically test this, a Mann-Whitney test was carried out. For this, a null hypothesis (*H0*) that inferred a non-significant difference in quality practices between ISO 9000 and non-ISO 9000 organisations as well as an alternative hypothesis (*H1*) which predicted a significant difference between these two groups were posed. The results of the Mann-Whitney test are presented in Table 8.

Insert Table 7 in here

Insert Table 8 in here

As illustrated in Table 8, the Mann-Whitney test revealed that all *p*-values were higher than the significance level (2-tailed) of 0.05 in all the evaluated constructs, indicating that equal variances can be assumed for the two groups in all categories. As a result, the null hypothesis (*H0*) cannot be rejected for any of the constructs. Additionally, the results from the test statistics, which provide the significance levels of the two-tailed test for every considered factor, suggest that there is not a significant difference between ISO 9000 and non-ISO companies with the context of their quality practices. This is confirmed from the fact that all *p*-values were much higher than the significance level of 0.05, and as a result the null hypothesis (*H0*) was accepted. Therefore, similarly to *H1* and *H2*, hypothesis *H3* was rejected for all the constructs of the European pharmaceutical manufacturers, a fact that indicates the neutral effect of the ISO factor on the LR level.

5. Discussion of results

RQ1. Are European pharmaceutical manufacturers capable of supporting lean manufacturing practices?

The results obtained from the analysis suggest that the participating European pharmaceutical manufacturers are still far from being supportive towards the adoption and/or sustainment of LM in their operations. This finding is in line with the observation of D'souza *et al.* (2007), who asserted that the majority of pharmaceutical companies have left behind the improvement of their manufacturing practices, as change in this area is mainly driven by compliance issues. According to Friedli *et al.* (2013), the pharmaceutical industry has focused on manufacturing products that just comply with current good manufacturing practices (cGMPs), without aiming at achieving excellence in their manufacturing operations. This could explain the results obtained from this research. In further support of the research outcome, the vice-president of operations of AstraZeneca claimed that manufacturing is not considered a core activity in the pharmaceutical industry (Friedli *et al.*, 2013) and as a result, the improvement of manufacturing practices has been neglected.

Although the results of this study support some elements of the literature, they may constitute an unexpected outcome. The majority of the participating firms have already implemented LM, partially or fully, and therefore they may have been expected to already have adequately developed their quality practices. The literature is full of references of LM in the pharmaceutical industry (Nenni *et al.*, 2014), and also of successful lean stories for large pharmaceutical manufacturers such as Lunbeck (Houborg, 2010), GSK (Carleysmith *et al.*, 2009), Novo Nordisk, Novartis and Abbott pharmaceuticals (Friedli *et al.*, 2013), all of which reported remarkable improvements in their manufacturing operations. Thus, keeping in view the significant amount of time that an operational excellence approach such as LM requires for its full deployment (Friedli *et al.*, 2013), the results obtained from this research may be explained based on the assumption that the participant organisations were in the early stages of the LM implementation.

In terms of the specific constructs, processes constituted the most develop among the participant firms as it achieved the highest mean score of 3.92. Within this construct, the strongest practice was that of personnel that control and operates the working zones, see Table 1, which was found to have a mean score of 4.38. This indicates the attention that has been given to the recruitment of qualified employees within the European pharmaceutical manufacturing industry, and can be attributed to the low level of automation in this industry, which mainly relies on manual processes (Friedli *et al.*, 2013). In this regard, Friedli *et al.* (2013) also highlighted the huge investments from pharmaceutical firms to bringing in high skilled resources over the past decade. On the other hand, the practice regarding the revision of cycle time for each product obtained one of the lowest scores (3.55) in the category of processes. This corroborates the findings of Shah (2004), who highlighted the lengthy cycle times in the pharmaceutical supply chain, and hence suggests that a minor development has been achieved in this area over the past decade.

The second highest scored construct was that of human resources (3.69), the importance of which in quality practices has been highlighted by various authors such as Achanga *et al.* (2005) and Furlan *et al.* (2011). Within this construct, the statement related to multitasking workers, see Table 1, obtained the highest score (3.97). This is in accordance with one of the principles of LM, which requires multiple tasks to be performed by workers in a specific work cell (McDonald *et al*., 2009). This is in accordance with the findings in the previous explained construct of process regarding the emphasis that has been given to the human factor within the European pharmaceutical manufacturing industry. On the hand, the practice of employees feedback, see Table 1, obtained the lowest score. This result indicates the need for more involvement of the employees of the European pharmaceutical manufacturing industry in the improvement of the manufacturing processes of their organisations, which constitutes a major requirement in LM (Hasle *et al*., 2012).

From all the six constructs, supplier relations constituted the least developed (3.52) for the case of European pharmaceutical manufacturers. Within this construct, the least developed practice corresponded to that of the inspection of raw materials; see Table 1, which suggests a lack of trust between the participating firms and their suppliers. This result puts into question the long-term relations that the majority of the respondents had established with their suppliers, as by considering that, a more trustful relationship, and in turn less inspection, of the purchased raw materials would have been expected. Therefore, despite the long-term contracts with their suppliers, the participating firms have not yet improved their actual relations with the latter, resulting on poor exploitation of the benefits that this kind of relationships provides (Womack *et al.*, 1990). Similarly, the second lowest score (3.29) was attributed to the practices of on-time delivery from the suppliers, which apparently fail to satisfy the need of their buyers in this respect. This is in accordance with the findings of Friedli *et al.* (2013), who reported the failure of long-term supplier relations to achieve JIT delivery.

H1: Small and medium-sized firms (SMEs) and large organisations differ significantly with regard to their quality practices in the European pharmaceutical manufacturing industry

This hypothesis examined whether the company size had a direct effect on the quality practices used by the participating firms. In general, the results of the study suggested that both large and SMEs European pharmaceutical manufacturing companies are similar in their quality practices. This result contradicts the findings of various authors including Bakas *et al.* (2011), White *et al.* (1999), Second (2010), Golicic and Medland (2007), and Shah and Ward (2003),

who accentuated that the size factor affects the application of LM practices in terms of major obstacles for SMEs compared to large organisations. On the contrary, the results are consistent with the findings of another group of authors, e.g., Garza-Reyes *et al.* (2015), Mallur *et al.* (2012), Bonavia and Marin (2006) and Al-Najem *et al.* (2013), who suggested that there is no difference between SMEs and large organisations in supporting LM.

Besides the negligible difference between the participating SMEs and large pharmaceutical manufacturers in their current practices, it could also be observed that the former were found to be more supportive towards LM practices as their mean scores indicate. However, as the survey did not involve questions or interviews regarding the factors affecting those practices (Al-Najem *et al.*, 2013), it is difficult to identify the specific reasons behind the results within the context of the first hypothesis. Nevertheless, these results can be attributed to the upswing of SMEs, which appear to now be playing a leading role in the world's economies (Schlogl, 2004). Additionally, and as suggested by Bakas *et al.* (2011), SMEs have a narrower hierarchical structure, which coupled with the absence of bureaucratic procedures might facilitate the implementation and/or sustainment of LM.

H2: There is a significant difference in the quality practices used by European pharmaceutical manufacturing firms with long-term supplier relationships compared to those with short-term relationships established

This hypothesis investigated whether the established relationships between the participating organisations and their suppliers had an effect on their quality practices and level of LR. The results of the study indicated that there was not statistical evidence to suggest the existence of a significant difference in the quality practices used by European pharmaceutical manufacturing firms with long-term supplier relationships compared to those with short-term relationships. This result is consistent with the findings of Friedli *et al.* (2010), who reported the disappointing results of a group of pharmaceutical firms that had established long-term contracts with their suppliers in their effort to implement JIT processes. Long-term relationships, however, seem to be more supportive for the construct of processes. This result is in accordance with the majority of researches in the field of LM, which suggest the diffusion of this approach to the whole supply chain, which starts with the establishment of long-term relations with the main suppliers (Panizzolo, 1998).

In addition to the above, the results of this research do not only fail to provide evidence of different quality practices of the participating firms based on their relations with suppliers but also question the findings of numerous researches with respect to LM and supplier relations. For example, the subject of Supply Chain Management and supplier relations, in terms of their selection processes, has been discussed by numerous authors in the academic literature, including Kirytopoulos *et al.* (2008) for the case of Greek pharmaceuticals and Helper (1991). In this case, Kirytopoulos *et al.* (2008) highlighted the crucial importance of a qualified and reliable supplier for success in the pharmaceutical industry, whereas Helper (1991) stressed the need for long-term relations with suppliers in order to effectively implement LM. In contrast, the results obtained from this study contradict these findings, indicating that there must be further research and discussion on this subject in order to generate more reliable conclusions.

H3: ISO 9000 certified pharmaceutical firms differ significantly with non-ISO 9000 pharmaceutical firms in Europe regarding their quality practices

This hypothesis aimed at investigating the effect of ISO 9000 on the quality practices and LR level of European pharmaceutical manufacturers. In general, the results of this study indicated that ISO 9000 certification has no effect on the quality practices, and hence LR level, of European pharmaceutical manufacturers. This is in line with findings of Al-Najem *et al.*

(2013), Sun (2000), Williams (1997) and Taylor (1995), who claimed that ISO 9000 does not serve as a platform for quality excellence programmes such as LM and TQM. Indeed, as Al-Najem *et al.* (2013) discovered for the case of Kuwaiti SMEs, ISO 9000 only contributes to the training of the workforce and managers.

On the other hand, the findings of this study contradict those of other scholars including Karthi *et al.* (2011), Gotzamani and Tsiotras (2001), Sadiq Sohail and Boon Hoong (2003), Idris *et al.* (1996) and Magd (2006), who asserted that ISO 9000 provides a significant improvement of the quality practices within the firms and simultaneously constitute a decisive step towards LM practices or TQM. For instance, Gotzamani and Tsiotras (2001) suggested that there is a considerable difference between Greek ISO and NON-ISO firms in their performance for the constructs of human resources, supplier and customer relations, leadership and quality related processes. Similarly Magd (2006) accentuated the contribution of ISO 9000 in the quality practices of Saudi firms. However, those conclusions cannot be confirmed for the case of European pharmaceutical manufactures. To conclude, the findings of this study, in conjunction with those of Al-Najem *et al.* (2013), Sun (2000), Williams (1997) and Taylor (1995), imply the negligible effect of ISO 9000 certification to operational excellence programmes, and by extension to the LR level.

6. Conclusions, practical and theoretical implications, limitations and further research

This paper investigates the LR level of the European pharmaceutical manufacturing industry through the study of some quality management practices related to LM. Overall, the results of the study suggest that European pharmaceutical manufacturing firms still require further development in all the investigated constructs (i.e. processes; planning and control; human resources; top management and leadership; customer relations; and supplier relations) of the practices if they are to effectively support or sustain LM.

In terms of the practical contributions of this research, its findings have relevant practical implications for the European pharmaceutical manufacturing industry. For instance pharmaceutical manufactures in Europe that intend to apply, or have already implemented, LM can refer to the findings of this research in order to identify whether they are or can be supportive of operational excellence initiatives such LM. In this case, the literature review in conjunction with the findings of the survey present those factors that must be enabled before implementing LM. Simultaneously, the participating firms that have already implemented LM have the opportunity to identify the areas where further development is required in order to reach the desired level of LR. Finally, as the current state of LM in the European pharmaceutical sector is examined, the results of this study can serve as a tool for the benchmarking of this industry. The theoretical contribution of this paper has been highlighted in Section 1, where it has been established that the academic literature lacks of a consensus regarding the applicability of LM in the European pharmaceutical manufacturing sector as well as the capability of the latter to support lean initiatives. Therefore, this research contributes by expanding the limited body of knowledge regarding LM in the European pharmaceutical manufacturing sector. In addition, the results of this research can be compared with those of similar researches in other industries and/or countries to determine, for example, what factors endowments, and to what extent, play a role and have an effect on the level of LR of different industries and countries.

Limited sample size (i.e. 37) and a five-item Likert scale, which does not give the respondents the opportunity to express their opinion in more detail, are considered the main limitations of this study. These are important to be highlighted for future studies to consider them when replicating, expanding or conducting similar researches. Hence, future research can

be conducted with a larger sample size and the inclusion of interviews to capture relevant qualitative information regarding, for example, the reasons behind the responses that were collected. Further insight into the LR level of European pharmaceutical organisations will be achieved by incorporating these two strategies when expanding this research.

Future research can also be specifically focused on either large or SMEs within the European pharmaceutical manufacturing industry. This would provide more specific knowledge regarding the characteristics that enable, or hinder, the implementation or sustainment of LM in this industry according to the company's size. Finally, three different factors, namely: company size, supplier relations and ISO 9000 certification, were examined regarding their effect on LR. Future research can also evaluate the influence of other factors such as location and financial conditions on LR to further develop the understanding of this phenomenon in the European pharmaceutical manufacturing sector.

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Table 1. Items for Section 2 of the questionnaire (adapted from Al-Najem *et al.*, 2013 and Garza-Reyes *et al.*, 2015)

	Practices	Practices
Processes	5S	1. The workshop is divided into different workplaces and each zone has a specific task.
	Cellular manufacturing	2. The processes used within similar operations are placed close to each other in order to eliminate unnecessary steps.
	Skilled people	3. Each working zone is controlled and operated by qualified and well-trained workers.
	5S	4. Each item/piece of equipment is labelled to ensure it is located in the right zone/location in the workplace.
	Pull	5. Production at each station is pulled by demand from the next station.
	5S and standardisation	6. A certain person is assigned as part of his daily activities to ensure that the workplace is clean and all tools/pieces of equipment are put back in their appropriate places.
	TPM	7. Equipment maintenance records are posted on the shop floor to be actively shared with employees.
	Cellular manufacturing	8. The process flow of material and components is smooth and continuous, as the equipment is grouped.
	Pull	9. Products are not produced unless orders for them are received from customers.

	TPM	10. Machine operators and staff are engaged in the scheduled maintenance of equipment so that machines are maintained on a regular basis by skilled people.
	Documentation	11. There is a well-documented configuration setting for each machine/piece of equipment to avoid uncertainty about how to reconfigure the equipment during changeover.
	Standardisation	12. The total cycle time is revised for each product on a regular basis in order to reach the optimum level.
Planning and Control	Problem solving	13. In order to improve production, a focus group of workers is conducted (on a regular basis) to help the company identify wastes and solve problems by generating new ideas and solutions, which are then submitted to the managers.
	Benchmarking	14. There is an awareness of the wider industry performance, and a clear strategy is followed to benchmark performance with the top-class firm (at a domestic and national level).
	Standardisation	15. There are standard routes for loading raw materials and removing end products, including a standard picking time.
	Problem solving	16. Problem-solving techniques such as Fishbone diagrams are used to identify the causes of quality problems.
	VM/KPI	17. Up-to-date charts showing defect rates, key performance indicators, progress and next job activity are displayed on the shop floor.
Customer Relations	Customer awareness	18. There is awareness of what product features customers value and are willing to pay for.
	Customer feedback	19. Feedback is sought regularly, and surveys/meetings are often held with customers to improve product design and quality, and service.
	Customer involvement	20. Customers participate in the initial design process.
	Customer relationship	21. Valued customers are brought into visit the plant in order to provide some ideas about quality control that the company can follow.
	Customer involvement	22. Customers help the company by providing information about their future demands.
	Customer involvement	23. There is a system in place for collecting customer complaints so that problems can be avoided in the future.
Supplier Relations	Quality suppliers	24. A clear strategy is in place by which to evaluate supplier performance in terms of quality, delivery and prices.
	Close suppliers	25. Local suppliers are used to avoid shipment delays.
	Supplier involvement	26. Suppliers are aware of product designs and participate heavily during design and development.
	Quality suppliers	27. Raw materials and purchased parts are not subject to incoming inspection as they come from qualified suppliers.
	No. of suppliers	28. Active steps are taken to reduce the number of suppliers in each category.
	Quality suppliers	29. Raw materials are received on time from the date of order.
	Supplier relation	30. Suppliers are cooperative and committed to maintaining a long-term relationship.
	Feedback to suppliers	31. Suppliers are provided with feedback regarding quality and delivery performance.
Human Resources	Involvement	32. Workspace layout is reconfigured regularly based on feedback from employees.
	Multi-tasking	33. Workers are able to perform different tasks.
	Participation	34. Shop-floor employees drive suggestion programme.
	Motivation	35. Numerous awards, incentive programmes and annual bonuses are available for employees who help to improve processes and eliminate unnecessary steps. The evaluation is based on group performance.
	Skilled People	36. Workers are qualified enough to contribute to solving problems, and are able to work as a team.
	Communication	37. Departmental and employee relations are good, and conflict barely occurs.
	Involvement	38. Each employee has a clear understanding of his job description.
	Training	39. Employees have undergone quality training in terms of developing their problem-solving capabilities and identifying non-value-adding activities.
	Empowerment	40. Workers are empowered to stop the production line if abnormalities occur.
	Participation	41. Suggestions and ideas from shop-floor employees are actively used and implemented.
	Teamwork	42. Employees act according to the interests of the group, rather than their individual interests.
Top Manag	Visible management	43. Top management encourages and coaches workers by visiting the workplace on a regular basis.
	Knowing people's capabilities	44. We locate our worker where they can use their skills, qualifications and experience.

	Job security	45. People have job security and workers are regularly promoted to managerial positions.
	Commitment to improvement	46. Company invests in training programmes and encourages cross-job training.
	Commitment to improvement	47. Company uses external experts/consultants on a regular basis to evaluate the overall company performance and to improve production and quality level.

Table 2. Mean scores of European pharmaceutical manufacturers

Descriptive Statistics					
	N	**Minimum**	**Maximum**	**Mean**	**Std. Deviation**
Processes	37	2.75	5.00	3.92	.614
Planning and Control	37	2.20	5.00	3.60	.823
Customer Relations	37	1.67	5.00	3.64	.727
Supplier Relations	37	2.75	4.90	3.55	.480
Human Resources	37	2.00	5.00	3.69	.707
Top Management and Leadership	37	2.20	5.00	3.57	.709
All Items	37	2.20	5.00	3.7	0.546
Valid N (listwise)	37				

Table 3. Group statistics for SMEs and large firms

Group Statistics					
	Company Size	**N**	**Mean**	**Std. Deviation**	**Std. Error Mean**
Processes	SMEs	11	4.06	.668	.201
	Large Companies	26	3.87	.594	.116
Planning and Control	SMEs	11	3.44	.999	.301
	Large Companies	26	3.67	.748	.147
Customer relations	SMEs	11	3.7	.623	.188
	Large Companies	26	3.61	.777	.152
Supplier relations	SMEs	11	3.69	.507	.153
	Large Companies	26	3.49	.464	.091
Human Resources	SMEs	11	3.71	.845	.255
	Large Companies	26	3.68	.658	.129
Top Management and Leadership	SMEs	11	3.67	.878	.265
	Large Companies	26	3.52	.640	.126
All Items	SMEs	11	3.76	.644	.194
	Large Companies	26	3.67	.511	.100

Table 4. Mann-Whitney test for *H1*

Ranks				
	Company Size	**N**	**Mean Rank**	**Sum of Ranks**
Processes	SMEs	11	20.95	230.50
	Large Companies	26	18.17	472.50
	Total	37		
Planning and Control	SMEs	11	17.23	189.50
	Large Companies	26	19.75	513.50
	Total	37		
Customer Relations	SMEs	11	19.95	219.50
	Large Companies	26	18.60	483.50
	Total	37		
Supplier Relations	SMEs	11	21.14	232.50
	Large Companies	26	18.10	470.50
	Total	37		
Human Resources	SMEs	11	19.05	209.50
	Large Companies	26	18.98	493.50
	Total	37		
Top Management and Leadership	SMEs	11	20.77	228.50
	Large Companies	26	18.25	474.50
	Total	37		
All Items	SMEs	11	20.05	220.50
	Large Companies	26	18.56	482.50
	Total	37		

Test Statistics					
	Mann-Whitney U	**Wilcoxon W**	**Z**	**Asymp. Sig. (2-tailed)**	**Exact Sig. [2*(1-tailed Sig.)]**
Processes	121.500	472.500	-.716	.474	.481
Planning and Control	123.500	189.500	-.651	.515	.523
Customer Relations	132.500	483.500	-.351	.726	.731
Supplier Relations	119.500	470.500	-.788	.431	.441
Human Resources	142.500	493.500	-.017	.987	.987
Top Management and Leadership	123.500	474.500	-.652	.514	.523
All Items	131.500	482.500	-.382	.702	.707

Table 5. Group statistics for companies with short and long-term relationships with their suppliers

Group Statistics					
	What kind of relationship the company has established with its major suppliers?	**N**	**Mean**	**Std. Deviation**	**Std. Error Mean**
Processes	Short-term relationships	6	3.76	.576	.218
	Long-term relationships	31	3.96	.626	.114
Planning and Control	Short-term relationships	6	3.69	.527	.199
	Long-term relationships	31	3.58	.884	.161
Customer Relations	Short-term relationships	6	3.74	.833	.315
	Long-term relationships	31	3.61	.714	.130
Supplier Relations	Short-term relationships	6	3.46	.483	.182
	Long-term relationships	31	3.57	.485	.089
Human Resources	Short-term relationships	6	3.79	.625	.236
	Long-term relationships	31	3.67	.732	.134
Top Management and Leadership	Short-term relationships	6	3.80	.566	.214
	Long-term relationships	31	3.51	.737	.134
All Items	Short-term relationships	6	3.71	.488	.185
	Long-term relationships	31	3.69	.566	.103

Table 6. Mann-Whitney test for *H2*

Ranks				
	Kind of relationship the company has established with its major suppliers	**N**	**Mean Rank**	**Sum of Ranks**
Processes	Short term relations	6	15.93	111.50
	Long term relations	31	19.72	591.50
	Total	37		
Planning and Control	Short term relations	6	19.93	139.50
	Long term relations	31	18.78	563.50
	Total	37		
Customer Relations	Short term relations	6	20.07	140.50
	Long term relations	31	18.75	562.50
	Total	37		
Supplier Relations	Short term relations	6	17.71	124.00
	Long term relations	31	19.30	579.00
	Total	37		
Human Resources	Short term relations	6	20.50	143.50
	Long term relations	31	18.65	559.50
	Total	37		
Top Management and Leadership	Short term relations	6	22.64	158.50
	Long term relations	31	18.15	544.50
	Total	37		
All Items	Short term relations	6	18.64	130.50
	Long term relations	31	19.08	572.50
	Total	37		

Test Statistics					
	Mann-Whitney U	**Wilcoxon W**	**Z**	**Asymp. Sig. (2-tailed)**	**Exact Sig. [2*(1-tailed Sig.)]**
Processes	83.500	111.500	-.835	.404	.413
Planning and Control	98.500	563.500	-.253	.800	.805
Customer Relations	97.500	562.500	-.292	.770	.776
Supplier Relations	96.000	124.000	-.352	.725	.747
Human Resources	94.500	559.500	-.408	.683	.690
Top Management and Leadership	79.500	544.500	-.995	.320	.330
All Items	102.500	130.500	-.097	.923	.925

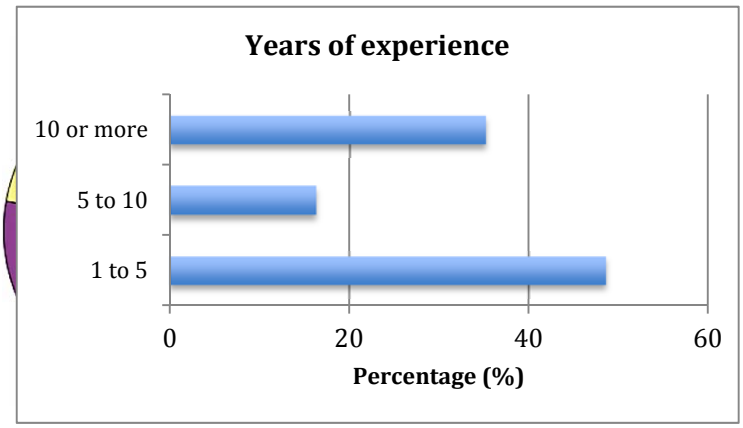
Table 7. Group statistics for ISO and non-ISO certified organisations

Group Statistics					
	Have you ever applied ISO 9000 in the company?	**N**	**Mean**	**Std. Deviation**	**Std. Error Mean**
Processes	ISO	17	3.93	.605	.147
	Non-ISO	17	3.92	.637	.142
Planning and Control	ISO	17	3.55	.899	.218
	Non-ISO	17	3.64	.775	.173
Customer Relations	ISO	17	3.60	.842	.204
	Non-ISO	17	3.67	.635	.142
Supplier Relations	ISO	17	3.51	.409	.099
	Non-ISO	17	3.58	.541	.121
Human Resources	ISO	17	3.52	.710	.170
	Non-ISO	17	3.83	.690	.154
Top Management and Leadership	ISO	17	3.48	.700	.132
	Non-ISO	17	3.64	.727	.125
All Items	ISO	17	3.63	.543	.132
	Non-ISO	17	3.75	.557	.125

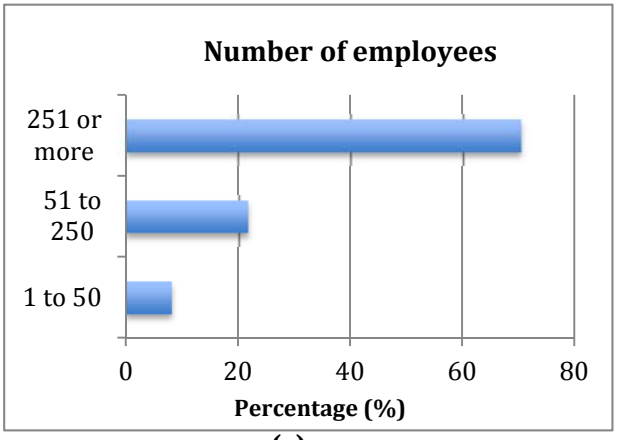
Table 8. Mann-Whitney test for *H3*

Ranks				
	Firm's Certification	**N**	**Mean Rank**	**Sum of Ranks**
Processes	Non-ISO 9000	17	19.00	380.00
	ISO 9000	17	19.00	323.00
	Total	34		
Planning and Control	Non-ISO 9000	17	19.45	389.00
	ISO 9000	17	18.47	314.00
	Total	34		
Customer Relations	Non-ISO 9000	17	18.68	373.50
	ISO 9000	17	19.38	329.50
	Total	34		
Supplier Relations	Non-ISO 9000	17	19.63	392.50
	ISO 9000	17	18.26	310.50
	Total	34		
Human Resources	Non-ISO 9000	17	20.45	409.00
	ISO 9000	17	17.29	294.00
	Total	34		
Top Management and Leadership	Non-ISO 9000	17	20.18	403.50
	ISO 9000	17	17.62	299.50
	Total	34		
All Items	Non-ISO 9000	17	19.90	398.00
	ISO 9000	17	17.94	305.00
	Total	34		

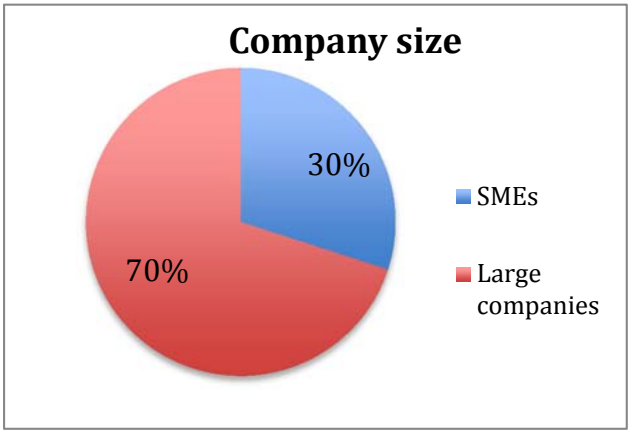
Test Statistics					
	Mann-Whitney U	**Wilcoxon W**	**Z**	**Asymp. Sig. (2-tailed)**	**Exact Sig. [2*(1-tailed Sig.)]**
Processes	170.000	323.000	.000	1.000	1.000
Planning and Control	161.000	314.000	-.275	.783	.798
Customer Relations	163.500	373.500	-.199	.842	.845
Supplier Relations	157.500	310.500	-.384	.701	.707
Human Resources	141.000	294.000	-.885	.376	.390
Top Management and Leadership	146.500	299.500	-.721	.471	.478
All Items	152.000	305.000	-.549	.583	.598


Years of experience
10 or more
5 to 10
1 to 5
0
20
40
60
Percentage (%)

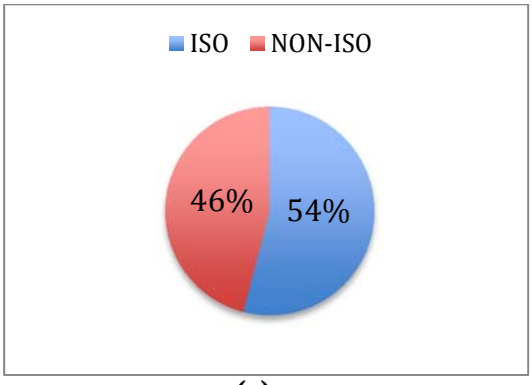
(b)


Number of employees
251 or more
51 to 250
1 to 50
0
20
40
60
80
Percentage (%)

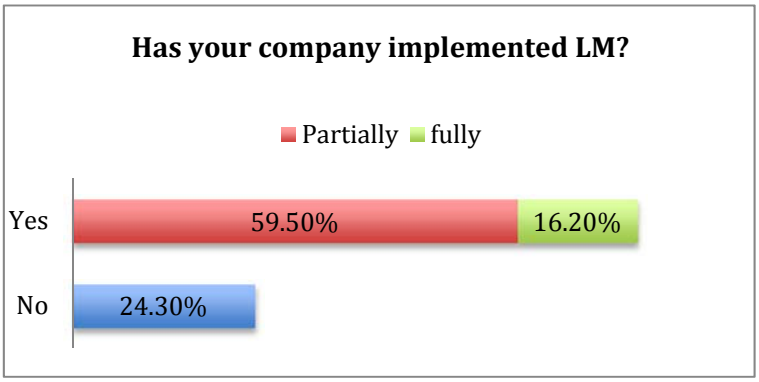
(c)


Company size
30%
70%
SMEs
Large companies

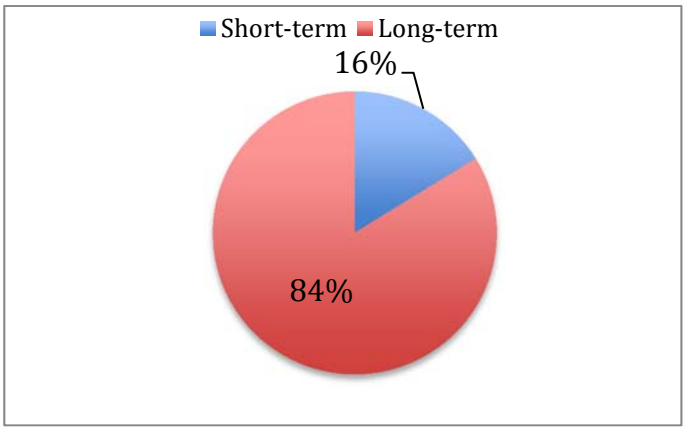
(d)


ISO
NON-ISO
46%
54%

(e)


Has your company implemented LM?
Partially
fully
Yes
59.50%
16.20%
No
24.30%

(f)


Short-term
Long-term
16%
84%

(g)

Figure 1. Profile overview of organisations and respondents – (a) Role of respondents and (b) years of experience, (c) Number of company's employees and (d) size, (e) ISO 9000 certification, (f) LM implementation, (g) relationship with suppliers