**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 implementLM 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.

**References**

Achanga, P.C., Shehab, E., Roy, R., Nelder, G. (2005), “Lean manufacturing for SMEs: enabling rapid response to demand changes”, *Proceedings of the 15th International Conference on Engineering Design (ICED)*, Melbourne, Australia, 15-18 August.

Al-Najem, M., Dhakal, H., Labib, A., Bennett, N. (2013), “Lean readiness level within Kuwaiti manufacturing industries”, *International Journal of Lean Six Sigma*, Vol. 4 No. 3, pp. 280-320.

Anand, G., Kodali, R. (2008), “Performance measurement system for lean manufacturing: a perspective from SMEs”, *International Journal of* *Globalisation and Small Business,* Vol. 2, No. 4, pp. 371-410.

Andersson, R., Eriksson, H. and Torstensson, H. (2006), “Similarities and differences between TQM, six sigma and lean”, *The TQM Magazine*, Vol. 18 No. 3, pp. 282-296.

Antony, J., Antony, F.J., Kumar, M., Rae Cho, B. (2007), “Six Sigma in service organisations: Benefits, challenges and difficulties, common myths, empirical observations and success factors”, *International Journal of Quality & Reliability Management*, Vol. 24, No. 3, pp. 294-311.

Antony, J., Desai, D.A. (2009), “Assessing the status of six sigma implementation in the Indian industry”, *Management Research News*, Vol. 32, No. 5, pp. 413–423.

Arya, A.K., Jain, S.K. (2014), Impacts of Kaizen in a small-scale industry of India: a case study”, *International Journal of Lean Six Sigma*, Vol. 5, No. 1, pp. 22-44.

Arya, A.K., Choudhary, S. (2015), “Assessing the application of Kaizen principles in Indian small-scale industry”, *International Journal of Lean Six Sigma*, Vol. 6, No. 4, pp. 369-396.

Bakas, O., Govaert, T., Van Landeghem, H. (2011), “Challenges and success factors for implementation of lean manufacturing in European SMEs”, *Proceedings of the 13th International Conference on the Modern Information Technology in the Innovation Processes of the Industrial Enterprise*, Tondheim, Norway.

Baker, P. (2004), “Aligning Distribution Centre Operations to Supply Chain Strategy”, *International Journal of Logistics Management*, Vol. 15, No.1, pp. 111-123.

Belekoukias, I., Garza-Reyes, J.A., Kumar, V. (2014), “The impact of lean methods and tools on the operational performance of manufacturing organisations”, *International Journal of Production Research*, Vol. 52, No. 18, pp. 5346-5366.

Bhasin, S., Burcher, P. (2006), “Lean viewed as a philosophy”, *Journal of Manufacturing Technology Management*, Vol. 17, No. 1, pp. 56-72.

Bhasin, S. (2012), “Performance of lean in large organisations”, *Journal of Manufacturing Systems*, Vol. 31, No. 3, pp. 349-357.

Bonavia, T., Marin, J.A. (2006), “An empirical study of lean production in the ceramic tile industry in Spain”, *International Journal of Operations & Production Management*, Vol. 26, No. 5, pp. 505-531.

Carleysmith, S.W., Dufton, A.M., Altria, K.D. (2009), “Implementing Lean Sigma in pharmaceutical research and development: a review by practitioners”, *R&D Management*, Vol. 39, No.1, pp.95-106.

Chatterjee, B. 2014, *Applying Lean Six Sigma in the Pharmaceutical Industry*, Gower Publishing Ltd, Surrey.

Chowdary, B.V., George, D. (2011), “Improvement of manufacturing operations at a pharmaceutical company: a lean manufacturing approach”, *Journal of Manufacturing Technology Management*, Vol. 23, No. 1, 56-75.

Chun Wu, Y. (2003), “Lean manufacturing: a perspective of lean suppliers”, *International Journal of Operations & Production Management*, Vol. 23**,** No. 11, pp.1349-1376.

Cooper, D.R., Schindler, P.S. (2013), *Business research methods*, 12th edition, McGraw-Hill, New York, NY.

Corbett, C.J., Luca, A., Pan, J. (2003), “Global perspectives on global standards: a 15-economy survey of ISO 9000 and ISO 14000”, *ISO Management Systems*, January-February, pp. 31-40.

Crowther, D., Lancaster, G. (2008), *Research methods in management: A Concise Introduction to Research in Management and Business Consultancy*, 2nd edition, Elsevier Butterworth-Heinemann, Oxford.

Cua, K.O., McKone, K.E., Schroeder, R.G. (2001), “Relationships between implementation of TQM, JIT, and TPM and manufacturing performance”, *Journal of Operations Management*, Vol. 19 No. 6, pp. 675-694.

Dahlgaard, J.J. and Dahlgaard, S.M.P. (2001), “Lean production, six sigma quality, TQM and company culture − a critical review”, *Conference Proceedings from the International Shanghai Quality Symposium*, November.

Devpura, M., Garza-Reyes, J.A., Kumar, V., Rocha-Lona, L., Soriano-Meier, H. (2014), “Exploring the application of quality improvement programmes and ISO standards in the Indian marble mining sector”, *International Journal of Productivity and Quality Management*, Vol. 13, No. 3, pp. 310-328.

de Winter, J.C.F., Dou, D. (2010), “Five-Point Likert Items: t test versus Mann-Whitney-Wilcoxon”, *Practical Assessment, Research and Evaluation*, Vol. 15, No. 11, pp.1-16.

Doolen, T.L., Hacker, M.E. (2005), “A review of lean assessment in organizations: an exploratory study of lean practices by electronics manufacturers”, *Journal of Manufacturing Systems*, Vol. 24**,** No. 1, pp.55-67.

Dora, M., Kumar, M., Van Goubergen, D., Molnar, A., Gellynck, X. (2013a), “Operational performance and critical success factors of lean manufacturing in European food processing SMEs”, *Trends in Food Science & Technology*, Vol. 31, No. 2, pp. 156-164.

Dora, M., Van Goubergen, D., Kumar, M., Molnar, A., Gellynck, X. (2013b), “Application of lean practices in small and medium-sized food enterprises”, *British Food Journal,* Vol.116, No. 1, pp.125-141.

D’souza, A.G., Keeling, D.J., Phillips, R.D. (2007), “Improving quality in pharma manufacturing”, Health Care, The McKinsey Quarterly, September, McKinsey&Company.

EMA (European Medicine Agency), (2014), “Annual report from the SME Office”, Available at: <http://www.ema.europa.eu/docs/en_GB/document_library/Report/2015/02/WC500181837.pdf> (accessed 28 February 2016).

Escanciano, C., Fernández, E., Vázquez, C. (2001), “Influence of ISO 9000 certification on the progress of Spanish industry towards TQM”, *International* *Journal of Quality & Reliability Management*, Vol. 18**,** No. 5, pp.481-494.

Freitas, I.M.B. (2009), “The diffusion of ISO 9000 and ISO 14001 certification, cross sectoral evidence from eight OECD countries”, *Summer Conference Papers*, pp. 17-19.

Friedli, T., Goetzfried, M., Basu, P. (2010), “Analysis of the implementation of total productive maintenance, total quality management, and just-in-time in pharmaceutical manufacturing”, *Journal of Pharmaceutical Innovation*, Vol. 5, No. 4, pp. 181-192.

Friedli, T., Basu, P., Bellm, D., Werani, J. (2013), *Leading Pharmaceutical Operational Excellence; Outstanding Practices and Cases*, Springer-Verlag Berlin Heidelberg, Berlin.

Furlan, A., Vinelli, A., Dal Pont, G. (2011), “Complementarity and lean manufacturing bundles: an empirical analysis”, *International Journal of Operations & Production Management*, Vol. 31 No. 8, pp. 835-850.

Garza-Reyes, J.A., Oraifige, I., Soriano-Meier, H., Forrester, P.L., Harmanto, D. (2012), “The development of a lean park homes production process using process flow and simulation methods”, *Journal of Manufacturing Technology Management,* Vol. 23, No. 2, pp. 178-197.

Garza-Reyes, J.A., Ates, E.M., Kumar, V. (2015), “Measuring lean readiness through the understanding of quality practices in the Turkish automotive suppliers industry”, *International Journal of Productivity and Performance Management*, Vol. 64, No. 8, pp. 1092-1112.

Ghobadian, A., Gallear, D. (1997), “TQM and organization size”, *International Journal of Operations & Production Management*, Vol. 17, No. 2, pp.121-163.

Golicic, S.L., Medland, S. (2007), “Size Might Matter: A Case Study of Lean Implementation in an SME”, *Society for Marketing Advances Proceedings***,** pp. 261-264.

Gotzamani, K.D., Tsiotras, G.D. (2001), “An empirical study of the ISO 9000 standards' contribution towards total quality management”, *International* *Journal of Operations & Production Management*, Vol.21, No. 10, pp.1326-1342.

Gupta, V., Acharya, P. and Patwardhan, M. (2013), “A strategic and operational approach to assess the lean performance in radial tyre manufacturing in India: a case based study”, *International Journal of Productivity and Performance Management*, Vol. 62 No. 6, pp. 634-651.

Hasle, P., Bojesen, A., Jensen, L.P., Bramming, P. (2012), “Lean and the working environment: a review of the literature”, *International Journal of Operations & Production Management*, Vol. 32, No. 7, pp. 829-849.

Helper, S. (1991), “How much has really changed between US automakers and their suppliers?”, *Sloan Management Review*, Vol. 32, No. 4, pp. 15-28.

Houborg, C. (2010), “Implementing A Successful Lean Program: Where Do You Begin?” *Pharmaceutical Technology Europe*, Vol.22, No. 9, pp.

Houser, J. (2008), Nursing Research: Reading, Using, and Creating Evidence, Jones and Bartlett Publishers, Sudbury, MA.

Idris, M.A., Mcewan, W., Belavendram, N. (1996), “The adoption of ISO 9000 and total quality management in Malaysia”, *The TQM Magazine*,Vol. 8, No. 5, pp.65-68.

Karlsson, C., Åhlström, P. (1995), “Change processes towards lean production: the role of the remuneration system”, *International Journal of* *Operations & Production Management*, Vol.15**,** No. 11, pp.80-99.

Karthi, S., Devadasan, S.R., Murugesh, R. (2011), “Lean Six Sigma through ISO 9001 standard-based quality management system: an investigation for research”, *International Journal of Productivity and Quality Management*, Vol. 8, No. 2, pp. 180-204.

Kirytopoulos, K., Leopoulos, V., Voulgaridou, D. (2008), “Supplier selection in pharmaceutical industry: an analytic network process approach”, *Benchmarking: An International Journal*, Vol. 15, No. 4, pp. 494-516.

Kumar, M., Antony, J. (2008), “Comparing the quality management practices in UK SMEs”, *Industrial Management & Data Systems*, Vol. 108**,** No. 9, pp. 1153-1166.

Lancaster, G. (2008), *Research methods:* *A concise introduction to research in management and business consultancy*, 2nd edition, Routledge, Oxford.

Liker, J. (2004), *The Toyota Way: 14 Management Principles from the World’s Greatest Manufacturer*, McGraw-Hill, New York, NY.

Liker, J.K., Choi, T.Y. (2004), “Building deep supplier relationships”, *Harvard Business Review*, Vol. 82**,** pp.104-113.

Liker, J.K., Meier, D. (2006), *The Toyota way Fieldbook, a practical guide for implementation Toyota’s 4P’s*, McGraw-Hill, New York, NY.

Mady, T.M. (2009), “Quality management practices: an empirical investigation of associated constructs in two Kuwaiti industries”, *International Journal of Quality & Reliability Management*, Vol. 26 No. 3, pp. 214-233.

Magd, H.A.E. (2006), “An investigation of ISO 9000 adoption in Saudi Arabia”, *Managerial Auditing Journal*, Vol.21, No. 2, pp.132-147.

Mallur, S.B., Hiregouder, N.L., Sequeira, A.H. (2012), “The relationship between TQM Practices and Business Excellence in Small and Medium Sized Manufacturing Enterprises of north Karnataka region”, Available at: <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2041439> (accessed on 28 February 2016).

Marvel, J.H., Standridge, C.R. (2009), “Simulation-enhanced lean design process”, *Journal of Industrial Engineering and Management*, Vol. 2, No. 1, pp. 90-113.

Mcdonald, T., Ellis, K.P., Van Aken, E.M., Koelling, P.C. (2009), “Development and application of a worker assignment model to evaluate a lean manufacturing cell”, *International Journal of Production Research*, Vol. 47**,** No. 9, pp. 2427-2447.

Mostafa, S., Dumrak, J., Soltan, H. (2013), “A framework for lean manufacturing implementation”, *Production & Manufacturing Research*, Vol. 1, No. 1, pp. 44-64.

Nenni, M.E., Giustiniano, L., Pirolo, L. (2014), “Improvement of manufacturing operations through a Lean Management Approach: A case study in the pharmaceutical industry”, *International Journal of Engineering Business* *Management*, Vol. 6, No. 24, pp. 1-6.

Nordin, N., Deros, B.M., Abd Wahab, D. (2010), “A survey on lean manufacturing implementation in Malaysian automotive industry”, *International Journal of Innovation, Management and Technology*, Vol. 1 No. 4, pp. 374-380.

O'rourke, D., Greene, A. (2006), “Lean manufacturing practice in a cGMP environment”, *Pharmaceutical Technology Europe*, Vol. 18, No. 10.

Panizzolo, R. (1998), “Applying the lessons learned from 27 lean manufacturers: the relevance of relationships management”, *International Journal of Production Economics*, Vol. 55, No. 3, pp. 223-240.

Pavlović, K., Božanić, V. (2012), “Lean and Six Sigma concepts: Application in Pharmaceutical Industry”, *International Journal for Quality Research*, Vol. 6, No. 1, pp. 23-28.

Robson, C. (2002), Real World Research, Blackwell, Oxford.

Rose, A.M.N., Deros, B.M., Rahman, M.N.A., Nordin, N. (2001), “Lean manufacturing best practices in SMEs”, *Proceedings of the 2nd International Conference on Industrial Engineering and Operations Management (IEOM)*, Kuala Lumpur, Malaysia, January 22-24, pp. 872-877.

Saad, S., Perera, T., Achanga, P., Shehab, E., Roy, R., Nelder, G. (2006), “Critical success factors for lean implementation within SMEs”, *Journal of* *Manufacturing Technology Management*,Vol.17, No. 4, pp.460-471.

Sadiq Sohail, M., Boon Hoong, T. (2003), “TQM practices and organizational performances of SMEs in Malaysia: Some empirical observations”, *Benchmarking: An International Journal*, Vol. 10, No. 1, pp. 37-53.

Saunders, M., Thornhill, A. and Lewis, P. (2012), Research Methods for Business Studies, 6th ed., Pearson Education Limited, Essex.

Schlogl, H. (2004), “Small and medium enterprises: Seizing the potential”, *Organisation for Economic Cooperation and Development, The OECD* *Observer***,** No. 243, May.

Second, B. (2010), “The Barriers to SMEs' Implementation of Lean Production and Counter measures-Based on SMS in Wenzhou”, *International Journal of* *Innovation, Management and Technology*, No. 1, Vol. 2, pp.220-225.

Selko, A. (2011), “Pharmaceutical's Lean Prescription”, *IndustryWeek*, Available at: <http://www.industryweek.com/companies-amp-executives/pharmaceuticals-lean-prescription> (Accessed 26 February 2016).

Serrano Lasa, I., Castro, R.D., Laburu, C.O. (2009), “Extent of the use of lean concepts proposed for a value stream mapping application”, *Production Planning & Control*, Vol. 20, No. 1, pp. 82-98.

Shah, R. and Ward, P.T. (2003), “Lean manufacturing: context, practice bundles and performance”, *Journal of Operations Management*, Vol. 21 No. 2, pp. 129-149.

Shah, N. (2004), “Pharmaceutical supply chains: key issues and strategies for optimisation”, *Computers & Chemical Engineering*, Vol. 28, Nos. 6-7, pp. 929-941.

Smith, K.L., Greenwood, M.R. (1998), “Developing Co-operative Buyer-Supplier Relationships”, *Journal of Management Studies*, Vol. 35, No. 3, pp. 331-353.

Sun, H. (2000), “Total quality management, ISO 9000 certification and performance improvement”, *International Journal of Quality & Reliability Management*, Vol. 17**,** No. 2, pp. 168-179.

Taylor, W.A. (1995), “Senior executives and ISO 9000: attitudes, behaviours and commitment”, *International Journal of Quality & Reliability Management*, Vol. 12**,** No. 4, pp. 40-57.

Wagner, K., Schulze, U., Farber, A. (2009), “Lean comes to Pharma”, Pharmaceutical Executive, Available at: <http://www.pharmexec.com/lean-comes-pharma-0> (accessed 25 February 2016).

White, R.E., Pearson, J.N., Wilson, J.R. (1999), “JIT manufacturing: a survey of implementations in small and large US manufacturers”, *Management* *Science*, Vol.45**,** No. 1, pp. 1-15.

Williams, N. (1997), “ISO 9000 as a route to TQM in small to medium-sized enterprises: snake or ladder?”, *The TQM Magazine*, Vol. 9, No. 1, pp. 8-13.

Womack, J.P., Jones, D.T., Roos, D. (2007), *The machine that changed the world: How lean production revolutionized* *the global car wars*, Simon & Schuster UK Ltd, London.

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 | 1. The processes used within similar operations are placed close to each other in order to eliminate unnecessary steps. |
| Skilled people | 1. Each working zone is controlled and operated by qualified and well-trained workers. |
| 5S | 1. Each item/piece of equipment is labelled to ensure it is located in the right zone/location in the workplace. |
| Pull | 1. Production at each station is pulled by demand from the next station. |
| 5S and standardisation | 1. 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 | 1. Equipment maintenance records are posted on the shop floor to be actively shared with employees. |
| Cellular manufacturing | 1. The process flow of material and components is smooth and continuous, as the equipment is grouped. |
| Pull | 1. Products are not produced unless orders for them are received from customers. |
| TPM | 1. 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 | 1. 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 | 1. 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 | 1. 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 | 1. 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 | 1. There are standard routes for loading raw materials and removing end products, including a standard picking time. |
| Problem solving | 1. Problem-solving techniques such as Fishbone diagrams are used to identify the causes of quality problems. |
| VM/KPI | 1. 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 | 1. There is awareness of what product features customers value and are willing to pay for. |
| Customer feedback | 1. Feedback is sought regularly, and surveys/meetings are often held with customers to improve product design and quality, and service. |
| Customer involvement | 1. Customers participate in the initial design process. |
| Customer relationship | 1. Valued customers are brought into visit the plant in order to provide some ideas about quality control that the company can follow. |
| Customer involvement | 1. Customers help the company by providing information about their future demands. |
| Customer involvement | 1. There is a system in place for collecting customer complaints so that problems can be avoided in the future. |
| **Supplier Relations** | Quality suppliers | 1. A clear strategy is in place by which to evaluate supplier performance in terms of quality, delivery and prices. |
| Close suppliers | 1. Local suppliers are used to avoid shipment delays. |
| Supplier involvement | 1. Suppliers are aware of product designs and participate heavily during design and development. |
| Quality suppliers | 1. Raw materials and purchased parts are not subject to incoming inspection as they come from qualified suppliers. |
| No. of suppliers | 1. Active steps are taken to reduce the number of suppliers in each category. |
| Quality suppliers | 1. Raw materials are received on time from the date of order. |
| Supplier relation | 1. Suppliers are cooperative and committed to maintaining a long-term relationship. |
| Feedback to suppliers | 1. Suppliers are provided with feedback regarding quality and delivery performance. |
| **Human Resources** | Involvement | 1. Workspace layout is reconfigured regularly based on feedback from employees. |
| Multi-tasking | 1. Workers are able to perform different tasks. |
| Participation | 1. Shop-floor employees drive suggestion programme. |
| Motivation | 1. 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 | 1. Workers are qualified enough to contribute to solving problems, and are able to work as a team. |
| Communication | 1. Departmental and employee relations are good, and conflict barely occurs. |
| Involvement | 1. Each employee has a clear understanding of his job description. |
| Training | 1. Employees have undergone quality training in terms of developing their problem-solving capabilities and identifying non-value-adding activities. |
| Empowerment | 1. Workers are empowered to stop the production line if abnormalities occur. |
| Participation | 1. Suggestions and ideas from shop-floor employees are actively used and implemented. |
| Teamwork | 1. Employees act according to the interests of the group, rather than their individual interests. |
| **Top Management**  **and Leadership** | Visible management | 1. Top management encourages and coaches workers by visiting the workplace on a regular basis. |
| Knowing people’s capabilities | 1. We locate our worker where they can use their skills, qualifications and experience. |
| Job security | 1. People have job security and workers are regularly promoted to managerial positions. |
| Commitment to improvement | 1. Company invests in training programmes and encourages cross-job training. |
| Commitment to improvement | 1. 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  Large Companies | 11  26 | 4.06  3.87 | .668  .594 | .201  .116 |
| Planning and Control | SMEs  Large Companies | 11  26 | 3.44  3.67 | .999  .748 | .301  .147 |
| Customer relations | SMEs  Large Companies | 11  26 | 3.7  3.61 | .623  .777 | .188  .152 |
| Supplier relations | SMEs  Large Companies | 11  26 | 3.69  3.49 | .507  .464 | .153  .091 |
| Human Resources | SMEs  Large Companies | 11  26 | 3.71  3.68 | .845  .658 | .255  .129 |
| Top Management and Leadership | SMEs  Large Companies | 11  26 | 3.67  3.52 | .878  .640 | .265  .126 |
| All Items | SMEs  Large Companies | 11  26 | 3.76  3.67 | .644  .511 | .194  .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  Long-term relationships | 6  31 | 3.76  3.96 | .576  .626 | .218  .114 |
| Planning and Control | Short-term relationships  Long-term relationships | 6  31 | 3.69  3.58 | .527  .884 | .199  .161 |
| Customer Relations | Short-term relationships  Long-term relationships | 6  31 | 3.74  3.61 | .833  .714 | .315  .130 |
| Supplier Relations | Short-term relationships  Long-term relationships | 6  31 | 3.46  3.57 | .483  .485 | .182  .089 |
| Human Resources | Short-term relationships  Long-term relationships | 6  31 | 3.79  3.67 | .625  .732 | .236  .134 |
| Top Management and Leadership | Short-term relationships  Long-term relationships | 6  31 | 3.80  3.51 | .566  .737 | .214  .134 |
| All Items | Short-term relationships  Long-term relationships | 6  31 | 3.71  3.69 | .488  .566 | .185  .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 |

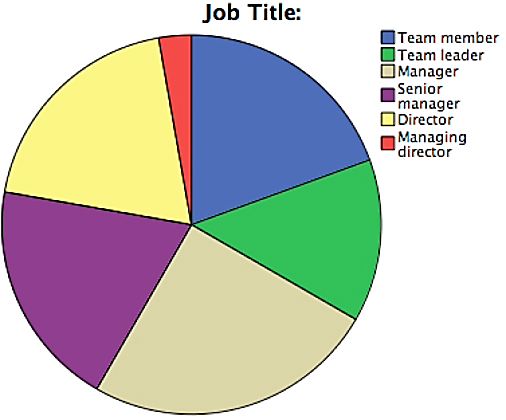
Table 7. Group statistics for ISO and non-ISO certified organisations

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



**(a)**

**(b)**

**(d)**

**(c)**

**(f)**

**(e)**

**(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