Prioritization of TQM practices in Brazilian medical device SMEs using Analytical Hierarchy Process (AHP)

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Abstract
The purpose of this article is to prioritize Total Quality Management (TQM) practices and examine their relative importance in TQM implementation in medical device small and medium enterprises (SME) using the Analytic Hierarchy Process (AHP) method. Mathematical modeling was the research method adopted in this article. The choice of AHP was based on the need to acquire knowledge from different companies and prioritize the most important TQM practices. Some implications are highlighted. Two strategic factors (Quality Management System and Quality Planning) and one tactical factor (Process Management) are strongly correlated and indicated by experts as having the major importance. Finally, The AHP method developed in the present study was shown to be useful for prioritizing practices relating to the implementation of TQM in medical device companies. The results can provide useful information to medical device managers to work upon the main practices in order to improve TQM performance.

Keywords: Total Quality Management, Analytical Hierarchy Process (AHP), medical device companies and small and medium enterprises.

Priorización de las prácticas de GCT en empresas de dispositivos médicos brasileños utilizando el Analytical Hierarchy Process (AHP)

Resumen
El propósito de este artículo es dar prioridad a Gestión de Calidad Total (GCT) prácticas y examinar su importancia relativa en la implementación de GCT en pequeñas y medianas empresas (PYME) de la industria de dispositivos médicos, utilizando el método de Analytical Hierarchy Process (AHP). Modelación matemática fue el método de investigación adoptado. La elección de AHP se basó en la necesidad de adquirir conocimientos de diferentes empresas. Algunas implicaciones se pueden destacar. Dos factores estratégicos (Sistema de Gestión de Calidad y Planificación de la Calidad) y un factor táctico (Gestión de procesos) están fuertemente correlacionados y indicados por los expertos como tener la mayor importancia. Por último, el método AHP desarrollado en el presente estudio ha demostrado ser útil para dar prioridad a las prácticas relativas a la aplicación de la GCT en las empresas de dispositivos médicos. Los resultados pueden ser información útil para los administradores de dispositivos médicos que trabajan en las principales prácticas con el fin de mejorar el rendimiento de la GCT.

Palabras clave: Gestión de la Calidad Total, Analytical Hierarchy Process (AHP), las empresas de dispositivos médicos y las pequeñas y medianas empresas.

1. Introduction
Total Quality Management (TQM) is a management approach, aimed at incorporating quality thinking in organizations, that became very popular in the 1980s [1]. TQM encompasses a set of principles, methods and practices that emphasize customer satisfaction, leadership, total employee involvement, continuous improvement, strategic and systematic approach, process management, factual approach to decision making, performance measurement and win-win supplier
relationships [2]. TQM is a managerial model for improving an organization’s competitive capacity and maximizing its participation in the market [3,4]. Several authors [5-7] have indicated that implementation of TQM improves organizational performance.

The literature includes many practices associated with TQM, but little attention has been paid to prioritizing such practices [8, 9]. Thus, it becomes critical to determine, among all such practices, those that most contribute to successful TQM implementation. Prioritization of these practices would ensure a better fit between the allocation of resources and the results achieved. Moreover, according to Bayazita and Karpak [10], although some companies successfully implement these practices, a considerable number fail in attempting to do so, which therefore justifies this research.

The Analytical Hierarchy Process (AHP) is a multi-criteria decision-making method for decisions that involve complexity and subjectivity [11]. AHP helps to solve problems that require prioritization, since it allows the complexity of unstructured decisions to be broken down into simpler components, thereby arranging a hierarchical order for each component of the analysis [11]. This paper presents the results of applying the Analytic Hierarchy Process (AHP) to evaluate TQM practices that are most important in TQM implementation in small and medium-sized Brazilian medical device manufacturers. A set of 19 TQM practices that most influence TQM implementation were identified from a literature review. Then, ten TQM experts were interviewed in order to establish the relative importance of these practices.

Brazilian companies in the medical device industry have made notable efforts towards implementing quality management in order to meet Brazilian standards and the requirements of international markets. In addition, Brazil is the largest producer and market for medical devices in South America and the country is both a major producer and a major importer in the region. This industry still only represents a small proportion of Brazil’s economy, but has many opportunities for growth in the coming years.

A number of similarities can be drawn between Brazilian and Colombian medical device industries; for example, their dependence on imports, growth perspective, predominance of small and medium enterprises (SMEs) in this industry, and the need to improve the quality of medical devices. Therefore, the contribution made by this paper is to systematize practices adopted in implementing TQM and classifying them in terms of priority. Furthermore, companies in the medical device industry would be able to improve their TQM implementation processes, further emphasizing practices that most contribute to the success of TQM implementation.

After this introduction, Section two presents a theoretical review considering practices involved in TQM literature and AHP method. The research method is described in Section 3, after which the results are presented, followed by a discussion of the key findings. Finally, conclusions are drawn.

2. Literature Review

2.1. Critical factors in implementing TQM

As indicated by several researchers [12,13], there are a number of benefits to implementing TQM: the improvement of a competitive advantage, higher profitability, fewer losses and less waste, higher productivity, improvement of product quality, employee skill development, greater customer satisfaction, higher motivation, operational improvements, continuous improvement of processes, and shorter waiting times.

Rockart [15] argued that the critical factors are good practices that should receive managerial attention given that they influence the performance of the organization positively. In addition, studies focusing on TQM practices have increased in recent years [14]. In this paper, practice can be understood as a principle, a method, a process or a tool that has a positive impact on the success of TQM implementation. From the TQM literature, 19 critical practices (critical factors) were identified and grouped into three categories: strategic factors, tactical factors and operational factors.

2.1.1. Strategic factors

Strategic factors represent the basis of TQM [8], and TQM principles are values that should be incorporated into organizational culture. The importance of these values has been confirmed by quality award prizes, such as the Malcolm Baldrige National Award, European Quality Award and even ISO 9001 standards [16]. Five TQM practices were identified as strategic factors: top management commitment (leadership), quality management system, continuous improvement, quality culture and quality planning.

The first strategic factor is the top management commitment (leadership), which is fundamental for creating an organizational environment in which people can become involved in quality objectives and customer satisfaction. Pheng and Jasmine [17] argue that if top management is not committed to TQM, it is impossible to achieve success in TQM implementation. Thus, several authors confirm that top management commitment is a strategic factor in TQM implementation [18-21].

Another strategic factor is the quality management system (QMS) that consists of a set of elements adopted by the organization in order to guarantee that its product and services meet customer requirements [22,24]. A QMS integrates organizational structure, processes, procedures, practices, roles, responsibilities, documents and resources within the organization and intends to provide a framework to direct and control an organization in terms of quality [23].

The second strategic factor is continuous improvement, which is a set of recurring activities that are carried out in order to enhance performance of processes, products, and services. According to Bessant and Francis [25] continuous improvement is an organizational process that guides an organization toward incremental improvements and requires involvement by everyone in the organization.

Creating a culture of quality is the fourth strategic factor. Organizational culture encompasses values, principles, attitudes and standards that influence organization members, defining their behavior. Consequently, quality culture encompasses an organizational behavior that aims to achieve customer satisfaction and quality improvements in whole organization [6,22]. According to Deming [26], a quality culture guarantees that an organization is involved in quality.

At the very least, the fifth strategic factor is quality planning,
which pertains to the Juran Trilogy [24] and focuses on setting quality objectives and specifying necessary operational processes and related resources to fulfill the quality objectives [23]. In this study, quality planning is stressed as it provides direction for TQM implementation.

2.1.2. Tactical factors

Tactical factors support the strategic factors and they sustain TQM implementation [8]. The following tactical factors were considered: employee involvement, reward systems and recognition, training and education, quality information systems, supplier relationships and process management.

First, employee involvement has been cited as one of the most important factors in TQM implementation [9,22,26]. It is essential to satisfy different stakeholders in an organization, and in order to achieve employee involvement, empowerment and delegation should be supported. Consequently, employees will develop knowledge, pursue quality goals and take on their responsibilities in ensuring quality [6,22,27].

The second factor is the reward system and recognition. Crosby [28] considers recognition as one of the most important factors in TQM. Moreover, since rewards and recognition practices increase employee motivation (which will influence customer satisfaction), it is necessary to create mechanisms for rewarding employees for their good contributions to the quality improvements [29].

Training and education are the third tactical factor. They provide qualifications and skills for employees in principles, methods and tools applied to quality management. Thus, training and education contribute to increasing employee skills and organizational competence [21,27,30].

The quality information system (QIS) is essential for implementing TQM because it generates data and information that are needed to make good decisions. Decision-making based on facts and data is one of the TQM principles, but this is achieved when the information is correct and available. Therefore, the quality information system is another critical factor in TQM [22,27]. In this study, QIS is the fourth tactical factor.

Mutually beneficial supplier relations (fifth factor) refer to the relationship between an organization and its suppliers. In TQM, a good and strong relationship can increase productivity and stimulate cooperation and collaboration in solving quality problems [23]. Thus, a win-win relationship needs to be established between the organization and its suppliers [30].

Process management is the last tactical factor considered in this study. The process concept induces a new way of thinking about organization and introduces customer satisfaction in all organization process [24,26]. Process management is a systematic approach to identifying key processes, ensuring a flow of activities and resources that adds value for the customer [6,22].

2.1.3. Operational factors

Operational factors are mainly methods and techniques. They are usually more visible and their results should appear in the short term [6,8]. The considered operational factors were techniques and tools for analyzing and problem-solving, teamwork, process mapping, visual management tools, benchmarking, statistical process control, suggestion plans, and customer surveys.

Problem-solving techniques are the first operational factor. They are simple tools used for solving quality-related operational problems [31]. The PDCA cycle, the seven basic quality tools, the seven managerial tools, and other techniques applied in continuous improvement activities are examples of problem-solving techniques [9].

The second factor is teamwork. TQM stimulates teamwork in order to overcome individual limitations and provide synergy in a group seeking quality improvements. Teamwork is considered essential for implementing TQM [7] and its promotion in an organization will demand cooperation, communication and a focus on the common goals [22,27].

The third factor comprises process mapping, which is the technique used to identify, improve and document the activities and resources that make up a business process. Several process modeling techniques can be applied for this purpose [32]. Process mapping is one of the techniques employed in the process management approach.

Visual management tools are the fourth operational factor. Quality information needs to be promptly available and visible to everyone, thereby facilitating decision-making [33].

The fifth factor is benchmarking and it is a method where an organization can compare its performance with other references (competitors, for example). It is also important for establishing higher standards and achievement improvements through learning from external experiences [6,22,27]. In this article, benchmarking is understood as an operational process developed by an organization in order to measure its performance and make improvements.

The Statistical Process Control (SPC) comprises a set of statistical techniques used for monitoring and improving production processes. It is essential in quality control, evaluating and promoting stability and the capacity of processes [4]. Thus, SPC is the fifth operational factor.

Suggestion plan is a structured strategy that seeks to stimulate the employee involvement. Through this practice, new ideas are creating and they can be implemented, which can generates improvement opportunities [31]. Suggestion plans constitute the seventh operational factor considered in this study.

The last factor is market research, which is any organized effort to gather information about customer needs. Capturing the voice of the customer and translating it into products specifications and process standards may represent a competitive advantage [7].

2.2. Analytical Hierarchy Process (AHP)

Shimizu [34] argues that the Analytical Hierarchy Process (AHP) is a structured technique for organizing and analyzing complex decisions that has received a lot of attention from academics and managers. This is confirmed by Wallenius et al. [35].

AHP aims to solve problems that arise when several criteria
are used in a single assessment. It breaks down the complexity of unstructured problems into simpler components. Therefore, it can be used to classify the importance of the factors considered in a decision-making process [36].

According to Saaty [36], AHP is carried out through pairwise comparisons and relies on the judgments of experts to derive priority scales. Moreover, expert judgments are taken into consideration by means of binary comparisons of factors in order to form a priority scale.

A judgment or comparison is a numerical representation of a relationship between two elements. Using comparisons in pairs in each judgment, the experts indicate which element of the pair is more important and then attribute weights in order to differentiate the relative importance of each element [11]. The judgments, inserted in the comparisons matrices, are often based on the fundamental scale of absolute numbers that is specific to AHP, as shown in Table 1.

According to Salgado et al. [38], the weights of the criteria and the priorities for the alternatives are obtained by means of judgments provided by experts. These judgments are inserted into a matrix (A) so as to pair the data. In this method, the importance values for the criteria are obtained using the eigenvector \( \mathbf{w} \) of the comparison matrix \( A \), as shown in Equation 1, where \( \lambda_{\text{max}} \) is the maximum eigenvalue.

\[
A \mathbf{w} = \lambda_{\text{max}} \mathbf{w}
\]  

The eigenvalue is a measurement of the consistency of the comparison matrix. In a matrix that is 100% consistent, a relationship of transitivity, \( a_{ij} = a_{ik} a_{kj} \), is supported for all comparisons. In this case, \( \lambda = n \), where \( n \) is the order of the matrix. However, in the AHP method, to ensure the consistency of the pairwise comparison matrix, the consistency judgment must be checked for the appropriate value \( \mu \), as showed in Equation 2:

\[
\mu = (\lambda - n)/(n - 1)
\]  

For a comparison matrix that is 100% consistent, \( \mu = 0 \) because \( \lambda = n \). Saaty [11] recommends that for values of \( \mu \) greater than 0.20, the comparisons should be reviewed. Review of the comparisons is a systematic procedure for improving the decision-making process. The largest eigenvalue \( \lambda_{\text{max}} \) is estimated by means of the arithmetic mean of the elements of the consistency vector.

The number of comparisons is a quantitative attribute and is the inverse of the performance of the application of the multi-criteria method. The larger the number of comparisons, the greater the effort needed to achieve decision-making. More comparisons may consume more resources [38]. Thus, \( x \), the number of comparisons needed for completing a comparison matrix, can be obtained using Equation 4.

\[
x = n(n - 1)/2
\]  

To conclude, AHP has been employed successfully in different contexts. Sarathy [9] applied it in assessing quality management practices in the construction industry. In the same way, Salgado et al. [38] has used AHP to identify critical activities in new product development. In the case of this article, AHP will be used to prioritize TQM practices in the medical device industry.

3. Method

The research method was based on the works of Talib et al. [8], Lewis et al. [12], Kumar et al. [13], Khanna et al. [39] and Souza Junior et al. [40]. It follows the stages described below:

- **Review of the literature**: The literature on the main topics covered in this study was reviewed in order to identify and systematize the most critical factors in implementing TQM. Concerning AHP, the aim was to describe the procedures for applying AHP in complex problems.
- **Hierarchy of factors**: After the identification of TQM practices, they were divided into three categories (strategic factors, tactical factors, and operational factors). These categories and practices are shown in Fig. 1. There are three decision-making levels considered in this study. The first level represents the objective of the study; the second level of prioritization represents the categories of practices (criteria); and lastly, the third level represents the prioritization of TQM practices (sub criteria).
- **Construction of binary comparison matrices**: Four matrices were designed: a general comparison between the factors in the second level of periodization (strategic, tactical and operational) and one matrix per category. Simplified spreadsheets were used to make it easier for the experts to fill them in.
- **Selection of experts**: In the selection of the experts, criteria such as the field of activity, academic and

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**Table 2.** Random Consistency Index (RI)

<table>
<thead>
<tr>
<th>n</th>
<th>RI</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
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</tr>
<tr>
<td>2</td>
<td>0.00</td>
</tr>
<tr>
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<td>0.58</td>
</tr>
<tr>
<td>4</td>
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</tr>
<tr>
<td>5</td>
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</tr>
<tr>
<td>6</td>
<td>1.24</td>
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<td>9</td>
<td>1.45</td>
</tr>
<tr>
<td>10</td>
<td>1.49</td>
</tr>
</tbody>
</table>

Source: [36].

For a comparison matrix that is 100% consistent, \( \mu = 0 \) because \( \lambda = n \). Saaty [11] recommends that for values of \( \mu \) greater than 0.20, the comparisons should be reviewed. Review of the comparisons is a systematic procedure for improving the decision-making process. The largest eigenvalue \( \lambda_{\text{max}} \) is estimated by means of the arithmetic mean of the elements of the consistency vector.

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- **Selection of experts**: In the selection of the experts, criteria such as the field of activity, academic and
professional experience, and availability to attend interviews were taken into consideration. Following these criteria, ten experts took part in this study. Four were academics in the field of quality management and have experience in developing projects in medical device companies. Six were TQM managers in medical device companies and they held the responsibility for implementing TQM.

- Application: Interviews were conducted in which pairwise comparisons were made based on the matrices that had been made for this purpose. The results from the judgments were aggregated using the principle of Aggregation of Individual Priorities (AIP) [41]. AIP is used when a group of individuals have no association or common goals, and, as such, tend to act according to their preferences, values and goals. It is noteworthy that experts are from different companies, and that the choice for the AIP was made because it is necessary to keep this individual analysis. Furthermore, the arithmetic mean was used to aggregate the judgments.
- Analysis of the results: Finally, the results of prioritization process were analyzed.

4. Findings and Discussion

At the second level of prioritization, the interviewees were asked to make a pairwise comparison of the three categories of factors (criteria). Table 3 shows the values after normalization (sum of the elements in each column of the judgment matrices with subsequent division of each element of these matrices by the sum of the values of the respective column), along with the local priorities among these criteria. The consistency ratio (CR) index was calculated, and this indicated that there was consistency between the pairs of criteria. The upper limit for the consistency index is 20% and the maximum result obtained in this study was 4.0%, which means that the data can be considered consistent [11].

Table 3 shows the priorities among the three categories of factors: strategic factors (0.6370), tactical factors (0.2583) and operational factors (0.1047). These results are in accordance with the studies developed by Talib et al. [8] and Souza Junior et al. [40]. Therefore, strategic factors are considered more important than other factors, which mean that the success of TQM implementation depends on the emphasis made on such factors.

In the following, the experts made judgments relating to TQM practices within each category (sub criteria). The results are presented in Tables 3 to 5. As mentioned before, the local priorities and consistency ratios were also calculated for each category of factors.

Table 4 shows TQM practices classified as strategic factors. The experts considered “top management commitment” (0.2698) as the most important strategic factor, and the development of a “culture of quality” is considered the second most important practice in this category (0.2663) with a score that is very close to the first factor. These two practices emphasize that successful TQC implementation depends on the ability to align individual and collective attitudes in seeking customer satisfaction. Moreover, this alignment should be supported by the top management commitment with the quality. The importance, the examples, and resources provided by top management and driven to improving quality will contribute to creating a quality culture, putting quality at the center of organizational culture.

This is truly important for SMEs, where the leadership has a great influence on management and performance. Company owners participated directly in activities and had the final say in quality issues. Although the findings are similar to those found by Talib et al. [8], they differ from the result found by Lewis, Pun and Lalla [19], for whom “top management commitment” and “culture of quality” occupies the 10th and 13th places, respectively, in terms of importance.

The quality management system (QMS) is the third most important strategic factor (0.1929). Particularly in Brazilian medical device companies, three main norms and standards have been used as references for structuring QMS, namely:
ISO 9001:2008, ISO 13485:2004, and Good Manufacturing Practices (GMP). Certifying their QMS according these standards has been encouraged in the medical device industry due to customer demands (some international clients for example) and Brazilian legislation (all medical device companies should at least have GMPs implemented). Although QMS is only the third factor, its implementation influenced the first two factors, given that the role of leadership is one of the main requirements of these standards.

Concerning the tactical factors, the experts highlight three factors as being the most important in implementing the TQM: “employee involvement” (0.2862), “process management” (0.2163), and “training and education” (0.1833). Together, they account for 68.58% of the relative importance of this category (Table 5). These findings coincide with the eight principles of quality, and agree with the results presented by Sarathy [9]. However, in terms of prioritization, they are not similar to studies by Talib et al. [8] and Souza Junior et al. [40].

Getting people involved in quality and providing them with training and education are fundamental in TQM. Although these findings are widely recognized, they represent challenges for SMEs due to their lack of resources and skills. The lack of resources in SMEs compared to larger enterprises may contribute to favor approaches that are more informal in SMEs. As such, this situation reinforces the need for investment in motivating and training employees. While these two practices affirm the human side of quality, they are not similar to studies by Talib et al. [8].

Table 6 shows the priorities given to TQM operational practices. Observing the local priority values, it can be concluded that there is no single method or tool that really stands out in relation to the others. “Statistical Process control” (0.1905) is considered the most important practice, but it is closely followed by the following factors: “Problem-solving Techniques” (0.1585), “Teamwork” (0.1523), and “Market Research with customer” (0.1497). As expected, there is a relationship between the most important operational factors with the most important tactical factors. Teamwork and Problem-solving Techniques provide the basis for training and involving employees. The values for other practices are shown in Table 6.

The findings shed light on the role of technical capabilities in supporting the TQM implementation. In addition, they stress the need to improve employee skills in using quality tools, especially those applied in solving problems and controlling processes. Empirical research developed by Oprime et al. [31] has also established a positive relationship between technical capabilities and success in TQM implementation.

In a further analysis, the overall priority of the criteria and sub criteria (i.e., considering the relative importance of each practice) was calculated considering the 19 investigated elements. Table 7 presents these results. The column “Geral priority” was calculated using the values presented in the “Local Priority Column,” however for each specific practice, it was necessary to multiply for its related category. For example, the value of local priority related with the practice “TMC” (0.2698) was multiplied for the value of local priority category “Strategic factors” (0.630).

Table 7 highlights that “top management commitment” (0.1719), “culture of quality” (0.1606) and “quality management system” (0.1229) are the three main practices indicated by the experts. These should therefore be emphasized in implementing TQM in SMEs in the medical device sector. On the other hand, the practices with the lowest relative importance belong to the operational factors category: “visual management tool” (0.0086), “suggestion plans” (0.0086), and “benchmarking” (0.0056).

The results shown in Table 7 are strongly influenced by the weights given to the categories placed in level 2. For this reason, all of the strategic factors are more important than the tactical and operational factors, and the tactical factors are more important than the operational factors. This reinforces that a successful implementation of TQM depends on a managerial approach that involves leadership, commitment, and integration of quality improvement into the management system.
Table 7
Overall priorities for the 19 TQM implementation practices

<table>
<thead>
<tr>
<th>Level</th>
<th>Factor categories and TQM practices</th>
<th>Local priorities</th>
<th>Overall priorities</th>
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<tbody>
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<td></td>
<td></td>
<td>Local Priority</td>
<td>Geral Priority</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Local Ranking</td>
<td>%</td>
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<td></td>
<td></td>
<td>Geral Ranking</td>
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<td></td>
<td></td>
<td>63.70</td>
<td>63.70</td>
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<td>Level 3</td>
<td>Top Management Commitment (TMC)</td>
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</tr>
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<td>Level 3</td>
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Source: The author

5. Conclusion

The aim of this study was to investigate and categorize the TQM practices and prioritize them on the basis of their relative importance for TQM implementation in the Brazilian medical device SMEs.

As SMEs suffer with the lack of resources and cannot allocate equal amounts of efforts or resources to each TQM practice, the findings of this study are very important in providing insights for medical device SMEs as they can evaluate their current practices and re-allocate reasonable resources to improve their TQM performance. Besides medical device SMEs, managers from other health organizations (i.e., hospital or health public systems) can also use these findings for selecting and evaluating their own suppliers.

From the TQM literature, 19 TQM practices were identified and they were grouped into three categories of factors (strategic, tactical, and operational). Subsequently, ten experts were consulted and, with the aid of the AHP (Analytical Hierarchy Process) method, it was possible to prioritize these practices. The TQM practices identified cover a wide range of activities from strategic, to tactical, to operational factors. Therefore, medical device SMEs should focus on the factors and practices that these experts considered of highest priority for TQM implementation.

Considering the results of this study, it is possible to present some managerial implications. One first managerial implication of this study is that the results indicate that TQM implementation is complex. Its success depends on strong commitment by top management, on the capacity to incorporate quality values in the organizational culture, and on the need to create involvement among collaborators (the most important practice at tactical level) in planning, controlling, and quality improvement activities. Although the three factor categories are important, TQM will not be successful unless human and political dimensions are also considered.

Another important managerial implication is the importance given to structuring a Quality Management System. Two strategic factors (Quality Management System and Quality Planning) and one tactical factor (Process Management) are strongly correlated and they were pointed out as having a major importance. QMS implementation
needs to be supported by an organizational structure, technical procedures, and commitment.

In conclusion, the leadership of top management and the creation of strong organizational values emphasizing quality are the main drivers for the organizational transformation promoted by TQM. Specifically, in the case of the medical device companies, the QMS is not the ultimate purpose or the main factor ensuring success in implementing quality. For the experts, the factors (top management commitment and culture of quality) are requisites for implementing the QMS as well as the TQM.

Finally, the AHP method developed in the present study was shown to be useful for prioritizing practices relating to TQM implementation in medical device companies. It can be useful to decision-makers as a guideline for implementing TQM and in evaluating the effectiveness of their current TQM practices.

Even though this study provides implications for academics and for medical device companies, it also presents some limitations. One of them is that its results are limited in scope because it relies on the judgments of only 10 experts. The second limitation is that research on critical factors in implementing TQM is not new and that many of the results found in the present study have been pointed out previously. However, it is important because the discussion on TQM practices is contextualized for the small and medium medical device companies, which have their own organizational and structural characteristics. Due to the similarity between Brazilian and Colombian medical device companies, the results can help TQM managers from both countries.

Future research could expand the number of experts including more TQM managers from medical device companies. Another proposal is to validate the criteria and sub-criteria proposed in this research using different research approaches, such as case studies or surveys. This would help to provide complementary information to develop appropriate strategies for improving the success of TQM in medical device companies.

References


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