# Analysis of total quality management (TQM) implementation in the biotechnology industry

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**Abstract.** Over the past two decades, the relevance of the Total Quality Management (TQM) model has increased significantly. TQM is becoming increasingly popular as organizations focus more on improving the quality of their products, services, and internal operations to increase customer value and gain competitive advantage. Organizations from the biotechnology sector play a significant role in the development of the national economy, the social sphere and employment. In such a situation, they face strong competitive advantages of competitors from all over the world, such as low costs and high productivity. The change in the amount of added value alone over the last 10 years leads to an increase of 35.2% per year. In 2009 is BGN 12 million, and in 2019 is BGN 208 million. That is why it is critical for them to improve their organizational performance through the Total Quality Management (TQM) approach. The purpose of this paper is to analyze the individual components of TQM in organizations from the field of biotechnology and food industry and to determine its model in terms of engineering activities. Pre-designed questionnaires were used as a data collection instrument in the present study. Conducting semi-structured interviews with team leaders in a biotech manufacturing organization provides insight into the impact of TQM on competitiveness. These elements, leadership skills and supplier/customer relationships have been found to play an important role in improving overall performance.

## 1 Introduction

Modern organizations are complex structures that are created to achieve certain corporate and/or individual goals. For their successful achievement, it is necessary to interact with multiple factors from the environment. Rapid technological development in the last decade has led to fierce competition in different parts of the world. Therefore, in order to survive, organizations prioritized their efforts to improve their overall performance. Those who manage to improve the added value they offer to customers globally become leaders in a given market.

Total Quality Management (TQM) is a key approach for organizations on the path to continuous improvement in a dynamic internal and external environment. To achieve high quality, it is necessary for the organization to determine its potential customers and their current and future needs [1]. TQM is a management philosophy that includes a set of principles that an organization implements and coordinates to ensure that the processes performed are directed toward customer requirements. It includes all units, departments and elements of the organizational structure. Top management in the management process formulates the overall strategy and customer-focused operations by establishing an appropriate company culture in which all employees are involved. Ensuring high quality is more complicated when employees with widely differing levels of professional education work in the organization or the subject of activity is offering an educational product/service [2].

The total quality management approach is comprised of several complementary concepts. First of all is the term "Total", which expresses the presence of integration or participation of all employees who are involved together in the process of providing the relevant product or service [3]. This so-called comprehensiveness in quality management emphasizes the presence of continuous process improvements involving everything and all activities together [4]. In the second place is the term "Quality", which in the context of overall management of the organization should be defined as: "Meeting the wishes and expectations of customers in the best way with the achievement of an economically justified profit" or from another point of view as "a dynamic state that meets or exceeds customer requirements, needs, expectations and desires" [5]. In TQM, continuous improvement processes are initiated by customers and are also adapted to changes in their requirements. And in the third place is the term "Management", which in a broader or even comprehensive sense is used as "management" and includes within itself the two components described above.

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In a high competitive environment, it is almost impossible to achieve the quality desired by customers without the presence of professional management and leadership abilities of top management [6]. This management concept, as well as others in the field of quality, involves the involvement of all employees, as everyone manages to manage their responsibilities best and in the right direction - roles in a team, position in the organization and formal status in the accepted structure.

The biotechnology sector in Bulgaria is highly competitive and has been developing rapidly over the last decade. These changes are also reflected in the field of education, where the interest of young students in specialties with this profile is constantly growing. These characteristics of the environment confront the sector with the need for dynamic changes leading to continuous quality improvements. The presence of highly pronounced globalization leads to rapid changes in the economic environment in which organizations must adopt new approaches to cope, survive and succeed. If their development in the considered sector follows traditional management models, they would hardly be able to improve their market position in view of the changing needs of customers in the market. Changes in organizational culture in the modern environment have been developing rapidly in recent years. This leads to new ways with new relationships between organizations, but there are still those that divert managers from key processes leading to higher competitiveness. Therefore, adopting another management approach such as TQM in management systems will shift the focus from simply doing more work to doing quality work. Organizations in the sector must continue to improve the working environment and the assets used, but if they do not involve all employees in the process of change, these partial changes will not lead to the achievement of corporate goals. Therefore, it is important to build the philosophy aimed at management through total quality, which will meet the new challenges facing the development of the biotechnology sector. This approach represents a different way of thinking, an effort to rethink the known possibilities for performing a given activity or process.

## 2 Materials and methods

The organization selected for this study is an innovation and technology leader in the development and production of beverage and food raw materials. Top management applies a creative approach to the creation of a broad product portfolio used by manufacturers of soft drinks, fruit juices, alcoholic beverages, confectionery, dairy products and ice cream, tobacco, snacks, baked goods and bakery products. The organization manufactures over 3.000 standard products for more than 2.000 customers in 42 countries around the world. Over the years, interesting products based on fruits, herbs and other natural ingredients have been developed, with a proven positive effect on human nutrition. The implementation of initiatives related to the TQM approach should help the development towards continuous improvement in a way that combines nature, technology and business.

The implementation of the present research is part of a large-scale project related to the rapid transformation of world trends into innovative concepts for the production of high-quality food and beverages. The use of questionnaires based on the key principles underlying TQM and semi-structured interviews aims to investigate the role and attitudes of employees towards the implementation of a management style and work leading to the creation of strong competitive advantages. The process of self-assessment through questionnaires and follow-up interviews enables the organization to clearly identify its strengths and areas where improvements can be made, developing into planned improvement actions that are continuously monitored. The activities of collecting and structuring information related to the description of the organization and its subsequent analysis, as part of the conducted self-assessment, can be carried out with the help of various models and approaches. Some of them are related to the use of simple questionnaires, meetings with senior management and middle management staff or a real simulation when applying for a quality award, etc. Guided by the individual characteristics of the organization and the improvement efforts, questionnaires are a fit-for-purpose tool based on people's opinion.

The process begins with preparation related to gathering information about the subject of the organization's activity, its organizational and management structure, team formation, etc., and based on the received data, an evaluation of the selected model. During the stage of planning and execution, answers are given to specific questions related to the time of conducting, the technology of conducting, the tools used for conducting, carrying out the research, etc. During the implementation of stage three, processing of the received primary data, evaluation and analysis of the results in relation to the selected model is carried out. The implementation of stage four requires the team performing the self-assessment process to create a plan for improving the activities based on the data received and analyzed, describing the activities, the time for their improvement, and the employees involved in this process.

The follow-up interviews aim to provide additional information on how two of the TQM principles impact overall performance. These respondents were selected for the interview based on their project management experience and position in the management structure.

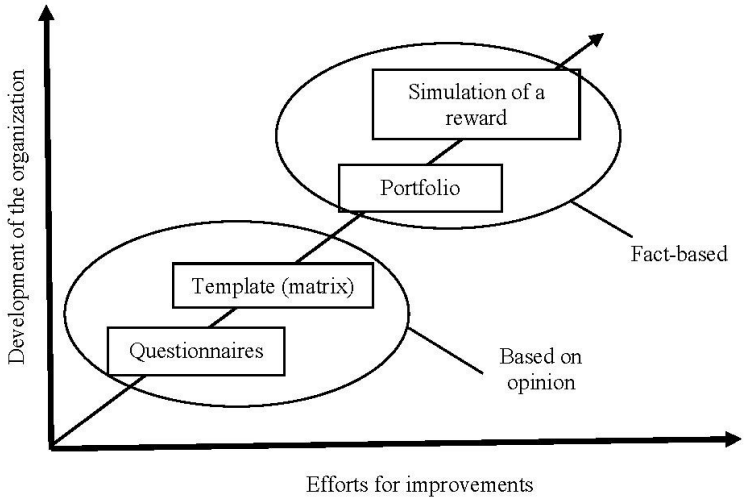


**Fig. 1.** Description of self-assessment methods

All respondents were assured of the confidentiality and anonymity of their responses and the intent of the interview and research, as data and information will be presented in a subsequent research paper. Based on an analysis of part of the questionnaires, the results of the study are presented in the next section.

## 3 Results and discussion

### 3.1 Total quality management (TQM)

The philosophy of total quality management (TQM) is defined as a system of practices with a comprehensive or systematic impact on organizational activities, processes and performance [7]. It is generally accepted that TQM is an integrated management philosophy aimed at continuously improving the performance of products/services and related processes in order to meet and exceed customer expectations [8]. TQM can also be defined as a management method leading both to the improvement of key competitive advantages and to an increase in market share in a relevant economic sector [9].

The TQM approach is characterized by a strong focus on achieving high quality, which helps managers to prevent the existence of problems in order to achieve continuous improvement of available market positions. This attitude towards the quality of the processes should be implemented in all management levels in the organization, covering all the basic functions carried out on a daily basis - planning, organizing, coordinating, controlling and motivating. In addition, the adoption of this philosophy should also be considered as a tool for holistic management, which aims to continuously improve all value-adding processes in the organization. This can only be successfully achieved if a unified quality management concept is applied from resource acquisition to customer service and after-sales care. [9, 10]

However, in parallel with the adoption of TQM as a management approach among scientific researchers, there is no lack of criticism related to the lack of a corrective function in the presence of a discrepancy with the real economic environment. Research on the topic shows that there is relatively little attention paid to the key principles leading to successful implementation and the reasons why certain organizations attempt to implement them and subsequently give up. A number of studies in the field show that achieving success in implementing TQM is largely related to the need for senior managers to take personal responsibility for the process by ensuring that a majority of employees, or at least key employees, will be involved in its implementation [11].

Although TQM is widespread as a strategic approach to quality management, as market conditions change, it is expected that competitive advantages will also change, with quality becoming one of the "core criteria" and flexibility, leadership, customer relationships, suppliers and innovation will assume the role of "key criteria for competitiveness". This paper aims to investigate the factors of leadership skills and supplier/customer relationships that are associated with the successful implementation of TQM programs in the biotechnology sector. Therefore, the research question developed for this study is identified as "How do the human, managerial, technical and contextual aspects of a biotech manufacturing organization influence the effectiveness of implementing TQM to improve its competitiveness?". There are reasonable assumptions that, despite numerous studies of the relationship between TQM and the effectiveness of the organization in mass prevention of the accepted principles, there are still no clear and indisputable practical examples of their influence on the effectiveness of R&D activities.

Looking at a specific sector of the national economy, we can assume that the relationship between the external environment and internal organizational culture is key to achieving success in implementing TQM. Therefore, the variations in the implementation of the philosophy are due to a large extent to the distortion of this relationship in one direction or the other, as well as the lack of coherence and adaptation to a customer in a particular market. Based on

the principles underlying TQM, some of the changes in organizational performance in the biotechnology sector could be explained by the presence of several key factors: leadership skills and relationships with suppliers/ customers.

### 3.2 Leadership skills

According to one of the popular theories, leadership is defined as behavior related to management activities, which to a certain extent represents one of the problematic areas for understanding and application, both for the management student and for managers in a real practical environment. Since the definition of TQM is not only tied to continuous quality improvements, but also to the understanding that people are a key resource in this process, there is a tendency to choose an appropriate management style. The most appropriate leadership style for successful implementation and sustainable application of TQM principles is characterized by personal participation, encouragement to bind others who are most closely related to a given process, especially in the phase of its definition. Thus, leadership skills linked to a strong commitment to quality through vision and strategy, organizational culture and clear goals defining performance improvements will greatly facilitate the implementation of continuous improvements [12, 13]

Reasonable assumptions in this direction are associated with the fact that the imputation of vision, mission and ideological goals strengthens the perception of employees regarding the meaning and importance of the specific task assigned to them. Thus, charismatic leaders have the opportunity to create a strong emotional connection between employees and their work by increasing their motivation to complete it on time and qualitatively according to the accepted standards. The combination of different characteristics defines the presence of an effective contextual vision that gives a role and form to modern leadership behavior. Managers in the top management must be committed and involved in the processes of applying the principles of TQM. In such a competitive environment, they necessarily lead and direct the efforts to achieve high quality, involving all employees in the processes providing added value for customers. Persistence and persistence are essential for the practical realization of innovative leadership skills and knowledge. In a similar way, the requirement for inter-functional cooperation in dealing with problems related to the quality of products/ processes and encouraging employees to conduct a constructive dialogue in this direction is also applied. All these are key factors that play an important role in the implementation of effective leadership leading to the achievement of goals related to the quality of performance in general.

When building strategic partnerships with suppliers or designing innovative products that meet customer requirements and are competitive in the global market, it is extremely important to have leadership skills applied by top management. Too often, personal commitment to TQM principles is weak or absent altogether, resulting in frequent employee complaints, resistance to change, and failure to implement changes aimed at improving quality. The described problems significantly complicate self-improvement and full use of the potential opportunities for continuous improvements that TQM provides.

A clearly defined and accepted leadership strategy in an organization helps significantly in achieving high quality and also leads to a change in the overall company culture. Thus, strong leadership expressed in constant commitment over time enables the organization to acquire new competitive advantages related to specific projects, processes and market segments. Such changes lead to the establishment of new organizational values and norms, emphasizing the leading role of quality in relationships with all interested parties.

**Table 1.** Sample of results according to the criterion **„Leadership skills”**

| Group | Lowest individual, % | Highest individual, % | Group average, % |
|---|---|---|---|
| **I** | 20.00 | 94.00 | 50.33 |
| **II** | 17.00 | 65.00 | 46.58 |
| **III** | 11.00 | 75.00 | 36.75 |
| **IV** | 12.00 | 83.00 | 56.40 |

The criterion evaluates the leaders in the organization, and the evaluation corresponds to the efforts made by the leaders to develop the vision, mission and values according to the principles of TQM. Unfortunately, their efforts stop here due to the lack of knowledge, skills and awareness about the culture of excellence at work. The developed values are taken for granted, not the day-to-day concern of leaders, and they are not accepted as role models. On the other hand, their attention is focused on managing day-to-day tasks well. There is still an outdated mindset among leaders that employee satisfaction is tied to getting a big enough paycheck at the end of the year.

Having a score of 11% among one of the questionnaires indicates that middle and lower level managers need interpersonal training. This would lead to greater efficiency in communicating with employees and recognizing their achievements.

**Positive aspects**

- There is a clear connection between the vision, the owner's priorities, the adopted strategy and the set goals.

- Leaders in the organization and in particular the owner strives for continuous improvement of the corporate strategy and its dissemination among all employees.
- Senior management actively participates in projects and initiatives related to improving the lives of residents in the area where the company operates and where the employees and their families live.
- There is evidence that leaders apply a systematic approach to motivating, supporting and evaluating employees at work.
- There is a built-in system enabling leaders to spread various organizational changes among all employees.

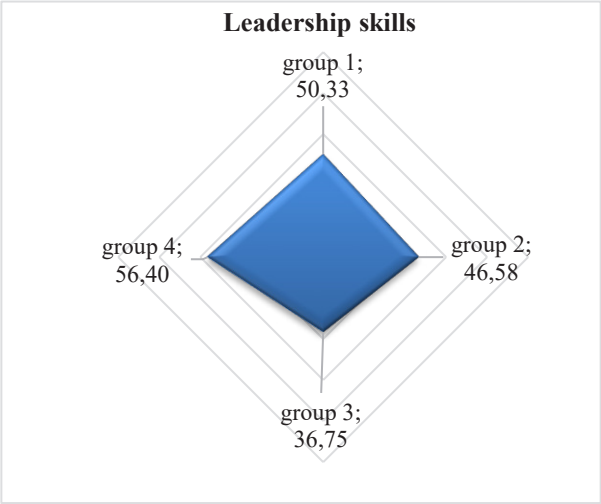


**Fig. 2.** Radar diagram of the studied groups according to the criterion **„Leadership skills"**

**Negative aspects**

- There is no evidence of a clear commitment of all leaders to the principles related to total quality management.
- There is no conclusive evidence that all employees in all departments accept the new changes and the drive for continuous improvement of work positively.
- There is some evidence that the implemented strategies are built after consultations with various stakeholders, but it is not clear how the consultations carried out support the policy and strategy.
- There is insufficient clarity regarding how some leaders ensure the efficient deployment of the employee performance evaluation process aimed at increasing their motivation.
- There is no clarity on how actions taken as a result of changes in work are monitored over a certain period of time.

### 3. 3 Relationships with suppliers/ customers

When implementing TQM, all activities and processes carried out by the organization are carried out in order to facilitate the needs of customers who appreciate the benefits of acquiring a given product or service. In this way, high customer satisfaction is achieved, customer loyalty is maintained and market share is expanded, which is a prerequisite for sustainable future success. The strong influence of the total quality management approach on customer relationship management is aimed at meeting and exceeding their expectations, which leads to improved competitiveness.

Clear and accurate dissemination of information among employees across organizational units leads to improved performance and efficiency. Despite the presence of specific benefits of implementing TQM, when the economic environment is not highly competitive and threats do not threaten the development of the organization, managers place less emphasis on activities aimed at satisfying customers [14]. Defining customer-supplier relationships as "Hard" components also implies less input into continuous performance improvement processes. However, this does not mean that these TQM components are not important, but other defined as "Soft" ones have a stronger impact on competitiveness.

A key point in implementing the TQM approach is for the organization to maintain close communication with its customers in order to uncover their needs and receive effective feedback. This information is necessary as it simultaneously understands to what extent their requirements have been met and what further improvements need to be made. In addition to this communication approach, suppliers also play a significant role in TQM, and hence on a number of quality indicators [15]. The presence of different levels of waste at the beginning of a production process can be associated with the raw materials, materials or components supplied to the organization.

**Table 2.** Sample of results according to the criterion **„Relationships with suppliers/customers"**

| Group | Lowest individual, % | Highest individual, % | Group average, % |
|---|---|---|---|
| **I** | 36.00 | 70.00 | 51.50 |
| **II** | 31.00 | 92.00 | 51.64 |
| **III** | 9.00 | 78.00 | 39.16 |
| **IV** | 12.00 | 77.00 | 47.45 |

Deteriorated values of this indicator may be due to improperly constructed relationships with suppliers, which necessitates additional investment in these relationships to achieve sufficient control over quality-critical inputs into the production system. In support of this, by implementing TQM, suppliers will provide input resources that are in exact quantity, time, quality, and price, which will enable the organization to maintain smaller-scale reserve stocks to use in a critical situation. Therefore, in order to achieve high efficiency in process

management, it is extremely important to emphasize quality when developing a supplier selection system [16]. The obtained evaluations according to this criterion are extremely important in view of the successful development of the organization dependent on its customers and suppliers. The evaluation is due to the results of a survey conducted by the employees, who are also internal customers for the organization's work. The relationship with suppliers and other partners is very good, based on mutual interest and goals.
The high ratings received for the survey overall indicate a positive trend in management's efforts to meet the ever-changing needs of customers. Proof of the reliability of the data is the fact that the organization is a desirable employer in the region and a correct partner among many companies around the world.

The lower result among one of the groups is explained by the opinion of the most pessimistic employees with more than 10 years of experience. They probably also suffered the most serious blows of the changes in the ownership of the organization in the years of transition, which causes their future mistrust.

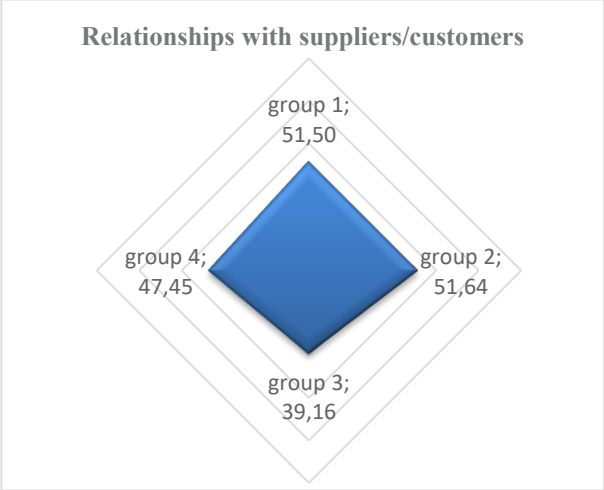


**Fig. 3.** Radar diagram of the studied groups according to the criterion **„Relationships with suppliers/customers"**

**Positive aspects**

- Equality is observed in the criteria used to evaluate the measures taken related to satisfying the current and future needs of customers.
- There is evidence of the implementation of consultations with clients, with positive results being observed in certain areas.
- There is evidence of striving for long-term and mutually beneficial relationships with various partners.
- There is some evidence of the company providing training to key external suppliers.
- At the time of conducting the self-evaluation process, the management started using a set of indicators to evaluate the company's performance.
- From the presented results for the work towards the clients, a positive development is also observed in individual processes and activities.

**Negative aspects**

- There is no definitive evidence determining which areas of the company's work are perceived positively by customers.
- There is no evidence of benchmarking with industry leading companies focused entirely on customer needs.
- There is no clear evidence of a process of learning from best practices through the benchmarking process.
- There is no evidence of obtaining information from suppliers to help management increase added value for customers.
- There is no evidence to compare the results obtained in this field within the company between the different departments, and against leading companies in the field.
- There is no evidence of the availability of reliable information from the indicators used, and its use for setting goals for improving work.

Considering TQM as a philosophy strongly aimed at satisfying the requirements and expectations of customers, this also includes identifying their characteristics, including both external and internal ones. Ensuring a close supplier-customer relationship enables managers to describe to a greater extent what the customer really wants and what they are really satisfied with. However, these quantitative parameters should be measured, monitored, analyzed and managed by professional analysts in the field. Otherwise, close contact with the customer can lead to a false sense of security, and in the absence of improvements, the first indicator of dissatisfaction can be a loss of market share - temporarily or permanently.

## 4 Conclusion

Management through total quality is a proven successful management philosophy, which is related to ensuring continuous and time-sustainable improvements of all business processes and the results related to their implementation. TQM remains a reliable approach that helps managers better address customer demands regardless of the turbulent economic environment around them. Historically, the change in implementation capabilities led to the adoption of quality distinguishing characteristics and fundamental principles that changed organizational culture and transformed TQM into a management paradigm. Important indicators are defined and the nature of processes and possible deviations are explained, applying key approaches ensuring high quality and competitiveness.

The successful implementation of TQM principles in the highly competitive biotechnological sector depends largely on the time factor. Changes made in a certain area will not have an immediate impact on compliance and customer satisfaction results. This is so because some of these changes are related to "soft" factors such as a change in the perception of quality, organizational culture,

internal motivation, etc. The key factors presented in the article are only a part of these components that enable managers to get ahead of their competitors precisely in terms of reaching customers with high-quality products.

The results of the conducted research show that managers better manage processes based on established technologies and activities, and encounter difficulties with those related to innovations. According to the employees, there is a high probability that the implementation of an innovative technology will create more problems in the development, production and realization of the products compared to an existing one. Often times in the field of biotechnology, a number of key processes go through preliminary simulation before being implemented in reality. In the organization in question, part of the employees at the middle management level accept that the processes based on new technologies give them the opportunity to create innovations and creative thinking. Many organizations in the sector carry out their activities by applying existing and already established technologies. Innovative ones are created and simulated in scientific organizations and then undergo transfer using the so-called open innovation model.

The research carried out showed that the change in the style of the leaders and the leadership skills they apply has an extremely strong influence on the employees who should be involved in the process of applying the TQM approach. The interviewees explained that in their organization every one of the senior management is directly involved in the principles underlying total quality. Based on the conducted research as a scientific-applied contribution is the creation of a practical program based on TQM, which aims to achieve zero defects for a certain time interval (1 year), implementing effective engineering methods. In addition to this, based on specific leadership skills, the organization has a competitive vision and strategy that is clearly communicated to all employees.

Regarding supplier/customer relationships, the organization has implemented a program that aims to ensure a mutually beneficial partnership, focusing on long-term cooperation with a smaller number of suppliers. This would reduce costs in the long term, which in the sector under consideration is a key competitive advantage. Information related to suppliers/customers is also shared in the internal information system with different levels of access, and is reported in a three-month period among all employees. As a result of a targeted policy towards customers, their needs are usually met and even exceeded. For the last five years, only positive reviews have been registered after external and internal audits. Regarding relations with employees and their empowerment in decision-making, there are indications of serious progress. This is especially strongly advocated in the formation of a company culture of self-managing teams, where employees are granted vacation time upon successful achievement of goals set by managers.

In the implementation of activities related to engineering operations, employees have the authority to decide whether to release a batch with a lower yield for implementation or not, as well as to make changes in the technological process. Among new team leaders with less than 5 years of industry experience, decision-making empowerment appears to be insufficiently effective, and they typically seek consultation with their supervisors before making important decisions.

Therefore, the present study should be continued in several ways. First, to create a model for implementing TQM in the biotechnology sector, which takes into account its individual characteristics. Second, to disseminate the model to stakeholders so that certain factors can be more precisely tailored to better explain the role of employee quality and knowledge in an organization. Third, the relationships found should be examined in different settings and markets to test their universality or multidirectionality, as well as the influence of random events on them. Finally, the description of a set of factors with clear causal relationships between them could ensure a rapid and successful implementation of TQM in the considered sector, improving its competitiveness as a whole.

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