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PROPOSITION OF A MODEL FOR QUALITY MANAGEMENT SYSTEM IMPROVEMENT

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ABSTRACT

The research proposes a system of improvement of a Quality Management System (QMS) in small and medium industries through the application of Six Sigma (SS) and Lean Six Sigma (LSS) methodologies. The main objective of the research is the development of an unprecedented reference model that aims at reducing the variability of restrictive resources, reducing losses, inefficiencies and waste, optimizing the cost-quality trade-off of products and processes, in addition to the consolidation of the Industry 4.0 concept. The methodological components include bibliographic, descriptive, technological and qualitative research. The proposed model, in the synergy between Lean Production and Six Sigma, strengthens and extends the longevity of an existing industrial quality system through continuous improvement cycles (kaizen) based on three large sets of orientative and sequential activities, so as to establish lean quality as strategic support throughout the operations network.

Keywords: Quality Management System; Six Sigma; Lean Six Sigma; Small and medium industries.

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1. INTRODUCTION

The direct relationship between competitiveness is linked to the development of new management methodologies and structures, as well as the improvement of manufacturing and industrial organization (Schumpeter; Mcdaniel, 2009). The competitive power of an industry depends on continuous improvements in productivity, quality and efficiency levels in all production processes, and the implementation, structuring and improvement of Quality Management Systems (QMS) are paramount to achieving consistency in meeting customer requirements (Anholon *et al*., 2018).

Goetsch and Davis (2015) and Martínez-Costa et al. (2009) argue that a quality system represents the initial milestone for establishing a quality-oriented business system, in addition to building a sustainable competitive advantage, encouraging continuous improvement of operations and profitability. These authors state that the QMS enables gradual and permanent reductions in production costs, including improving commercial performance and market share.

According to Ohler and Polt (1995), Small and Medium-sized enterprises (SMEs) need enabling models for the implementation and continuous improvement of quality systems as a way to improve product development, operations management and support activities – such as industrial maintenance, process engineering, factory design and product availability to end consumers. For Muller et al. (2016), PMIs have a great capacity to disseminate innovations and stimulate regional growth, as they have very flexible structures that are adaptable to the external environment, as well as generating great jobs in developing countries.

Preferably, SMEs need to understand that quality systems ensure product compliance, so that operational performance standards are continually improved to meet customer requirements (Kakouris; Sfakianaki, 2018). Thus, the QMS would be an opportunity for these industries to plan and design an organizational arrangement based on the principles of total quality and the approach to continuous process improvement.

Thus, the research problem is related to the difficulty inherent in most SMEs in systematically and safely executing projects for the implementation (and subsequent consolidation) of quality systems. The overall objective of the study was to develop a reference model to supplant the step-by-step improvement process of an already structured quality system, using the Six Sigma (SS) and Lean Six Sigma (LSS) methodologies, and the associated specific objectives were:

- Conduct bibliographic research in international bases on the themes related to the construction of the proposed reference model to improve the pre-existing quality system;

- Develop a referential model composed of sets of orientative activities to improve the quality system of small and medium industries.

Finally, as addressed in the formulation of the research problem, the relevance of this study was directly associated with the difficulties and limitations that most Brazilian small and medium-sized industries have in relation to the execution of continuous improvement projects in their quality systems. Therefore, the development of the applied guideline model, structured in sequential steps and guiding activities, should greatly facilitate the process of continuous improvement of more effective and sustainable long-term quality systems, resulting in increased competition power of these organizations.

2. LITERATURE REVISION

Quality Management System

The quality system concept sets policies and objectives to manage responsibilities and authorities for maintaining and improving the quality of products and processes. This concept can be considered a "competitive weapon", reducing production costs, improving rework rates, scrap and waste, as well as meeting end-user needs, contributing to increase the profitability associated with the portfolio of traded products (Bonato; Caten, 2015; ABNT, 2015).

The QMS represents a management model under the direct responsibility of top management that is based on identifying customer requirements, product and process consistency, and continually improving the entire production system (including suppliers and distributors). For Castillo-Peces et al. (2017), the goal of QMS is to standardize procedures and processes, as well as reduce inefficiencies in all activities present in a company's chain of operations, increasing the power of competition.

Bacoup et al. (2018) and Ost and Silveira (2018), propose that the purpose of a quality system is to ensure that products (goods and/or services) are always in compliance with engineering specifications, which depend primarily on determining clients' requirements – the effectiveness of QMS is associated with critical factors such as administrative structure, organizational culture and employee training. Therefore, the organization

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must have intensive training programs, decision-making, adequate information systems, policy and procedure reviews, and reward systems.

The structure of a QMS focuses on the prevention and detection of defects in products and processes by identifying/assessing needs and determining customer satisfaction, supplier qualification, critical project analysis, operational procedure design, and inspection routines, as well as production monitoring and control, personnel training, and maintenance/calibration of measuring instruments (Kumar *et al*., 2018).

The implementation of a QMS depends on the elaboration of work procedures, production methods, planning of product and process evaluation systems, and quality improvement programs (including materials received from suppliers). Dellana and Kros (2018) discuss the link between quality system and related standards, highlighting as key benefits direct communication with end consumers and potential customers, knowledge of products and processes, waste reduction, cost improvements, downtime, and productivity and quality.

In the same line of reasoning, Díaz and Martínez-Mediano (2018) argue that normative certification leads production organizations to implement quality assurance systems aligned with Total Quality Management (TQM), taking the principles present in the ISO 9001: 2015, which are summarized in customer focus, leadership, people engagement, process approach, improvement, evidence-based decision making, and relationship management.

According to ISO 9001: 2008, the structure of a quality system is based on five certifiable requirements, which can be explained as follows:

- Quality Management System: establishes the criteria for the elaboration and maintenance of the QMS documentary set, including records of all processes and activities developed;
- Management Responsibility: Aims to demonstrate senior management's commitment to leading quality assurance efforts through the implementation and proper functioning of the QMS;
- Resource Management: directs resources to manage quality in the organization (physical, human, infrastructure and work environment);
- Product Realization: aims to evaluate the activities related to production and the availability of finished products, including planning, customer relations, product development and design, materials procurement and manufacturing and process measurement/monitoring;
- Measurement, Analysis, and Improvement: they establish criteria and resources for measuring QMS-related process outcomes in terms of customer satisfaction, product and process compliance, as well as critically analyzing collected data, and promoting corrective, preventive, and improvement actions.

Based on ISO 9001: 2015, Fonseca (2015) argues that the process approach is essential to the functioning of a structured QMS, from a business system risk perspective, emphasizing the continuous improvement of processes and resulting products (goods and/or services made available to customers). Therefore, responsibility for process management is tied to all organizational levels and focuses on the principles of evidence-based decision making, people engagement, and relationship management.

Six Sigma

The Six Sigma Program aims to achieve a process quality level that is likely to produce no more than 3.4 Defects per Million Opportunities (DPMO) and can be understood as the natural continuity of TQM. This enables a drastic reduction of production-focused nonconformities, enabling the industrial organization to achieve Sigma capacity higher than traditional quality based on Statistical Process Control (SPC) through the use of improved statistical instruments, reducing product procurement costs and increasing productivity, which leads to greater market share (Marques; Matthé, 2017; Desai *et al*., 2012).

As pointed out by Antony et al. (2017), Six Sigma (SS) is a methodology for streamlining business processes by simultaneously optimizing the performance and variability of key activities, leading to significantly reduced losses, inefficiencies and waste, and contributing to increased profitability of operations and promoting innovation. In this sense, the Six Sigma Program is linked to the Industry 4.0 concept (self-learning of modern machine tools and the use of smart materials), where business processes must become increasingly intelligent with the incorporation of the knowledge and technologies associated with this program (Sony, 2018; Basios; Loucopoulos, 2017).

The main objective of SS is the search, identification, elimination of nonconformities, system failures and/or business processes, where the focus is to prioritize the performance of critical steps important to the satisfaction of consumers/end users. Furthermore, SS allows re-

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ducing the exaggerated variability of critical processes to add value to products, in order to adjust them to the nominal value of the specifications (centralization), making such products more robust and reliable to the consumer market (Suresh *et al*., 2012).

For the consolidation of TQM and the realization of SS projects in all functional areas (and not only in manufacturing), Marzagão and Carvalho (2016) advocate a peculiar organizational structure composed of mentors, team leaders, facilitators and coaches, which should be configured as follows:

- Master Black Belt - Employee who holds Black Belt status for a minimum of five years, recommended by industry top management, mentoring approximately five successful Black Belt candidates with strong technical, managerial, and team leadership skills, acting fully in corporate projects;

- Black Belt - an employee specializing in a set of Six Sigma methods, techniques and tools, working in a specific area (engineering, management, quality or finance) as well as preventing/solving cost reduction and quality improvement issues, and should have leadership and team building skills;

- Green Belt - Employee properly trained in the use of the Six Sigma instrumental ensemble, which does not need leadership skills, but assists in the execution of black belt projects.

SS addresses the redesign and management of organizational processes, where Define, Measure, Analyze, Improve and Control (DMAIC) is a script for performance improvement projects for existing processes, goods and/or services (Marques; Matthé, 2017). An SS project is executed through financial phases and targets (cost and/or profit optimization), and DMAIC is its main methodology combined with a statistical set of tools and management behavioral methods to improve business processes (Vrellas; Tsiotras, 2015). Define, Measure, Analyze, Design and Verify (DMADV) is a five-phase methodology that is the basis for execution for Design for Six Sigma (DFSS); it is applied to the design of new products and processes and is very similar to DMAIC (Aligula *et al.*, 2017).

DFSS is a method for developing new products and/or processes, acting as a script for the execution of interactive projects (set of collaborative activities between people and technologies). Thus, DFSS is employed in the development and design of new products and processes to achieve a Sigma class higher than 4.5 (Montgomery, 2013).

Liverani *et al*. (2019) and Gremyr and Fouquet (2012) argue that DFSS focuses on the design of products and/or processes that require operational flexibility (varying models) without compromising performance, reliability and cost characteristics, in addition to focusing on manufacturability, reliability and maintainability, and praising principles of Taguchi's robust design – decreased complexity of products and processes, concentration of efforts in the early stages of design and design of preventive mechanisms (poka-yokes). Thus, DFSS transforms the functional requirements from the "voice of the customer" into technical requirements and product specifications, then arriving at process configurations and ultimately obtaining a control plan for managing critical system parameters of the new integrated product-process design.

Lean Six Sigma

Lean Six Sigma (LSS) can be understood as a methodology for optimizing business processes by improving product and/or process quality, increasing operational flexibility, reducing production costs and making products available, in order to achieve very high levels of customer satisfaction. LSS combines instruments and principles from two well-established, complementary and synergistic methods of production optimization (Lean Production and Six Sigma). This ensures that problems that cannot be solved by applying single methods are addressed more broadly and consistently, favoring the execution of more complex improvement projects (Raval *et al*., 2018; Chugani *et al*., 2017).

In the industrial environment, Thomas et al. (2016) reinforce that Lean Production is directed to continuous process improvement in terms of workflow, loss elimination and productivity increase. Six Sigma, in turn, seeks to drastically reduce operational variability in order to achieve the concept of "full quality" in products and thus improve the level of service provided to consumers/end users.

For Mkhaimer et al. (2017) and Karthi et al. (2011), process documentation and quality system requirements are met and improved through the application of LSS, bringing benefits to industries of different sizes and business sectors – thus, in the QMS, the LSS assists the implementation of improved processes and in the compliance with new operating procedures. Gnanaraj et al. (2011) also argue that the realization of Lean Six Sigma projects in small and medium companies provides increased competitiveness and business expansion.

Moya et al. (2019) consider as important critical success factors that should be observed in the implementation of LSS:

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- Supplier selection/management through collaborative and standardized procedures;
- Realization of customer requirements through product development/design activities;
- Leadership, commitment from senior management, financial support, intense functional training and encouragement of teamwork to facilitate the realization of LSS projects;
- Organizational culture and project planning focused on the continuous improvement of products and processes;
- Regulatory certifications and experience using Just-in-Time and TQM instruments in improvement projects;
- Process measurement systems, data/information management (factual basis for decision making) and project management know-how.

Powell et al. (2017) comment that the value stream mapping technique associated with the LSS-adapted DMAIC methodology provides an important basis for understanding processes, in terms of identifying stages where there is a waste of product sourcing resources (unnecessary activities that do not add value).

From the perspective of the LSS, Duarte et al. (2012) argue that process reengineering occurs through the use of DMAIC to reduce variability, waste, operational inefficiencies, and repetitive unproductivity. This procedure reinforces that the success of Lean Six Sigma depends on the ability to identify priority projects that deliver robust results, but at the same time are executed through lean instrumentation, leading to lower lead time. Thus, the LSS application steps are:

- Definition of the process that should be improved, starting with the mapping of the integral value chain to delineate the business process, defining performance indicators, best practices and technology resources;
- Process characterization, which defines the structure and frequency of execution of activities, performance measurement, degree of automation, customer value added, costing and redundant processes;
- Process grouping (clustering) and identification of similarities in the execution of activities, in order to optimize the execution of the improvement project.

Finally, regarding the use of the LSS methodology by SME, Thomas et al. (2008) mention that improvement activities aim at the highest possible profitability, quickly recovering expenses after project completion, for such companies usually do not have the financial conditions to hire specialized support consultants. The authors also suggest a simplified SPC-based LSS application model, Quality Function Deployment (QFD), Value Stream Mapping, DMAIC, Taguchi Method, multivariate statistical methods, Overall Equipment Effectiveness (OEE), Housekeeping (5S) and Total Productive Maintenance (TPM).

3. METHOD

The methodological structure of the present work has characteristics of technological research, which aims to produce knowledge aimed at solving problems formulated in the research project to support the practical application, which can be carried out a posteriori, and may result in an action plan, script or intervention proposal that represents the basis for conducting action research (Gil, 2017).

The methodological approach of the work obeyed the qualitative research orientation that, from the Engineering point of view, allows the understanding of fundamentals and subjects relevant to the related object of study. Examples may be organizations, business environment or competitive context. The qualitative aspect also uses as data source/information the literature on a given theme, as well as the application of systematic methods of searching for knowledge for critical appreciation and synthesis of selected data/information. (Bernardes *et al*., 2018).

This research followed a descriptive basis that, as pointed out by Cauchick-Miguel (2019) and Ludwig (2015), implies the collection of data/information for detailed description of the study object characteristics and establishment of correlations between variables linked to the problem, seeking the deepening of knowledge through the explanation of the main aspects concerning epistemological exploration.

Thus, the present study was based on updated bibliographical research, and in Severino's view (2018), this modality represents the method of study execution, comprising the fundamental methodological procedure for the production of scientific knowledge, consisting in the selection of knowledge closely related to the research problem. Lakatos and Marconi (2017) argue that the bibliographic research supports the production of knowledge considered insufficient for the treatment of the object of study and that, among the materials used

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are books, encyclopedia entries, specialized magazines, journal portals available on the Internet, congress works, newspapers and magazines, separate technical publications, dissertations, and theses.

Thus, the systemic literature reviews, under the aspect of qualitative research, allow a greater understanding about the object of study, aiming to address the central research question. Subsequently, scientific articles and epistemologically correlated concepts will be sought. In turn, the research execution method (procedures) contemplates two steps defined as follows:

- Step 1 - Bibliographic survey on research topics (Quality Management System, Six Sigma and Lean Six Sigma);
- Step 2 - Development of the Six Sigma and Lean Six Sigma based reference model, consisting of three sets of guidance activities aimed at improving the SME quality system.

Finally, the proposed concise and objective methodological script was applied to the present study to facilitate the elaboration of an innovative referential model designed to improve the performance of quality management systems in small and medium-sized industries. This script has a pragmatic nature and its main concern was to assist the research execution.

4. PROPOSED REFERENCE MODEL

The reference model for the implementation of CEP--based quality assurance systems for application in small and medium industries is based on the following considerations:

The quality of products and processes is strongly associated with the needs, wants and expectations regarding consumers/end users ("customer voice");

The quality system has an interdependent relationship between organizational culture (linked values and behaviors), instrumental quality (norms, tools, techniques and methods), workforce commitment/engagement in productive and managerial processes (self-control);

The quality system should be based on four pillars: Product Design, Process Design, Product Realization, and After Sales. These pillars configure the Total Quality Tetrahedron, which is illustrated in Figure 1.

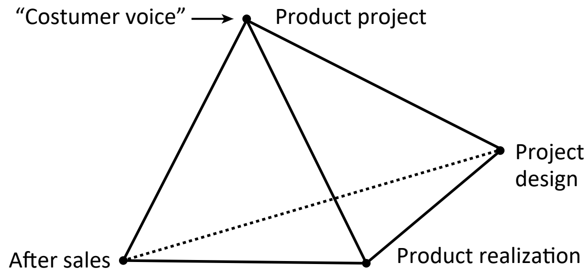

Figure 1. Total Quality Tetrahedron
Source: The author(s)

As illustrated in Figure 1, in a quality system, the first vertex (Product Design) assumes that the "voice of the customer" must be transformed into a documented design of the finished product (produced and marketed). The Process Design vertex refers to the elaboration of the technical design of the complete production process that is in absolute compliance with the product design, such as materials acquisition, chain of operations, and product availability. The third vertex (Product Realization) concerns the operationalization of the complete process related to the previously projected production chain (processes of materials acquisition, manufacturing, assembly, maintenance, inspection, sales, and product availability to customers). Finally, the After Sales vertex is related to the processes of customer/end-user service and technical assistance for field products, representing the total quality closed-loop that began (and was also finalized), with the concern to meet the requirements linked to the "voice of the customer".

The proposed reference model is based on two sequential and integrated steps to improve the performance of the industrial quality system, initially described as follows:

- Step 1 - QMS Improvement via Six Sigma, which aims at the execution of quality improvement projects to reduce the variability of critical products and processes, such as culture formation, team belts structure composition and instrumental ensemble concerning the Six Sigma Program;
- Step 2 - QMS Improvement via Lean Six Sigma, which represents the basis for continuous quality system improvement through the use of the LSS Program, resulting from the combination of Lean Production and Six Sigma, to optimize the cost--quality trade-off, referring to performance parameters of critical products and processes (consumer/end user health and safety, reliable product operation, and essential requirements for customer satisfaction).

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Therefore, the proposed referential model aims to assist improvement projects in pre-existing quality systems in small and medium-sized industries which, as already mentioned, have two sequential and interdependent stages. The first sequence is related to the selective application of the Six Sigma instrumental set in the industrial business system. In addition, the subsequent step is linked to more complex improvements in products and processes of great strategic relevance, considering the cost-quality paradox adequately addressed within the Lean Six Sigma Program.

Step 1 - QMS Improvement via Six Sigma

Stage 1 focuses on the application of the DMAIC and DMADV methodologies, as well as the consolidation of DFSS, elements aligned with the Industry 4.0 concept. Therefore, the focus should be on the implementation of improvement projects in products and/or processes considered fundamental for industrial competitiveness – this step also contributes to the development of new products and/or processes, facilitating the subsequent optimization of the critical points present in the Lean Six Sigma operations network.

In this sense, in Step 1, two blocks of activities were elaborated to improve critical business processes, the first of which is associated with DMAIC (enhancement of pre-existing critical products and/or processes). The second block concerns the use of DFSS/DMADV to support the development of new products and/or processes, as illustrated in Figure 2.

Based on a consolidated industrial quality system, in accordance with the instrumental set of statistical-quantitative basis (SPC), certified by NBR ISO 9001: 2015 and/or related sector standards, improvements are made to critical products and/or processes based on the DMAIC, where the first block of orientation activities is configured as follows:

- Promote multi-level functional training cycles for application of the instrumental set concerning the application of DMAIC;
- Build teams according to team belts logic and plan DMAIC project activities according to Project Management Body of Knowledge (PMBOK);
- Determine critical quality characteristics for product performance (related to customer requirements) that should be the basis for selecting/undertaking Six Sigma projects: (1) consumer/end user health and safety characteristics, (2) characteristics associated with expected product performance (full function integrity), and (3) quality inherent characteristics in terms of secondary and complementary product functions (important requirements for customer satisfaction);
- Perform diagnosis, mapping and characterization of the production process for authorized Six Sigma projects;
- Calibrate and measure "Six Sigma resolution" measuring instruments;
- Perform data/information collection and subsequent evaluation to identify the factors that influence the measurable critical characteristics of product quality and, subsequently, delimit critical process control parameters related to the mentioned quality characteristics;

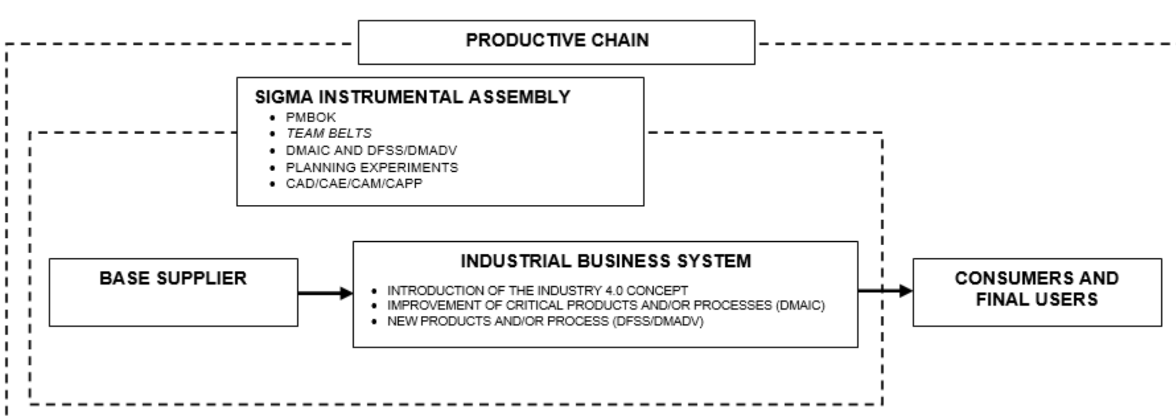

Figure 2. Step 1 Logical Structure (QMS Enhancement via Six Sigma)
Source: The author(s)

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- Analyze data/information collected to identify causes that impact critical process control parameters relative to critical quality characteristics;

- Evaluate and order (prioritize) critical process control parameters to perform activities related to the Taguchi Method (Design of Experiments/ DOE);

- Evaluate, according to the logic of the Taguchi Method, the behavior of critical quality characteristics for product performance through process experimentation - carry out planned tests/trials on critical process control parameters and analyze variations in specifications of said critical characteristics;

- Develop, based on the results of the Taguchi Method application, statistical models and correlations to determine the behavior of critical quality characteristics for product performance;

- Reconfigure ranges of critical process control parameters, establishing new optimized control parameters (new parameterization);

- Compose new improved process method (enhanced process documentation);

- Perform functional training based on the new improved method;

- Perform process follow-up to ensure that new critical process control parameters are stabilized and consolidated, ensuring that the new improved method is incorporated into the work routine;

- Prepare final report of the improvement project, record and archive lessons learned for consultation and support for new projects – which forms the basis of knowledge management associated with Six Sigma;

- Conduct periodic process audits to verify compliance with the new improved method (consolidation of the Six Sigma project results).

To develop new products and/or processes based on DFSS/DMADV, the second block of guidance activities is organized as follows:

- Promote multilevel functional training cycles for application of the instrumental set concerning the application of DFSS/DMADV;

- Build teams according to team belts logic and carry out the planning of DFSS/DMADV project activities according to PMBOK;

- Initiate authorized Six Sigma projects – conduct market research for data/information collection to determine customer requirements and feasibility analysis (commercial, technical and economic);

- Define, from market research results, product scope, initial sketches, Computer Aided Design (CAD) drawings, and functionalities;

- Use QFD Matrix to determine product requirements and their specifications/goal;

- Develop executive product design, such as conceptual modeling, Design For “X” (DFX) and detailed design in 3D CAD;

- Simulate product in Computer Aided Engineering (CAE), through the logic of the iterative cycle: design, build, test, optimize (in that order) in computational environment, until the approval of the detailed product design;

- Plan industrial production process through Computer Aided Process Planning (CAPP) for the approved product;

- Convert detailed product design (3D CAD) into Computer Aided Manufacturing (CAM) files, simulating manufacturing and rapid prototyping;

- Build product prototype - manufacture, by rapid prototyping through CAM, all the items that make up the product, including performing the final assembly;

- Perform tests/trials for prototype approval (homologation);

- Implement industrial production process, produce pilot batch, proceed to product certification and adjust capacity (ramp-up);

- Launch product, track product performance in the market (follow-up), as well as perform product and/or process improvements if necessary.

Finally, Step 1 of the proposed referential model (Improvement of QMS via Six Sigma) is supported by an activity guide aimed at improving the quality system in small and medium-sized industries, providing through

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DMAIC and DFSS/DMADV, the optimization of products and/or processes considered critical to the customer and the introduction of the Industry 4.0 concept. Therefore, the achievement of Step 1 is considered essential to the subsequent improvement of the industrial quality system through Lean Six Sigma, while optimizing production and quality costs (Step 2), which would, in a way, represent the achievement of the QMS maturity stage.

Step 2 - Enhance QMS via Lean Six Sigma

Step 2 is based on the use of the LSS Program to intensify quality system continuous improvement projects by optimizing the cost-quality trade-off of Six Sigma products and/or conventional Three Sigma processes, favoring the consolidation of the Industry 4.0 concept, as illustrated in Figure 3. Therefore, lean quality projects should be undertaken to simultaneously improve both overall quality and business system costs to further enhance industrial competitiveness. Regarding the criticality of products and/or processes that should be improved at this stage, it is linked to the three characteristics already defined in Step 1: consumer/end-user health and safety, expected product performance and requirements for customer satisfaction.

Thus, in Step 2 a single block of guiding activities was elaborated to either improve Six Sigma quality processes and/or products, as well as improve those conventional pre-existing QMS (and have Three Sigma quality levels), according to Figure 3. Considering that Lean Six Sigma is the fusion of two very widespread programs in the industrial environment (Lean Production and Six Sigma), it is emphasized that in Step 2, Six Sigma processes and/or products must be optimized from practically full application of the instrumental ensemble LSS. In turn, at this same stage, conventional Three Sigma processes and/or products are enhanced based on Lean Production tools, techniques and methods, prioritizing significant reductions in operating costs, as shown in the footer of Figure 3.

Assuming the existence of an already consolidated industrial quality system, as explained in Step 1, the single block of guidance activities for LSS application (Step 2) is configured as follows:

- Build teams according to team belts logic and plan PMBOK lean quality improvement projects for Six Sigma and conventional Three Sigma products and/or processes;

- Promote multilevel functional training cycles for application of the Lean Six Sigma instrumental set;

- Analyze and select products/processes that have already been improved through the application of DMAIC-DFSS/DMADV (Step 1), as well as conventional Three Sigma products/processes (related to pre-existing quality system);

- As per team belt defined for the selected project and based on the DMAIC methodology, perform phase D (Define) through the following tasks: assess expected project gains (financial benefits); prepare complete action plan for the proposed project; perform process mapping; approve initial project definition list through the stage-gate methodology;

- Perform phase M (Measure) by measuring critical process control parameters based on the key critical product quality characteristics, performing the following tasks: elaborate product value flow mapping for the current process state, stipulating measurement points; compose measurement plan of critical process control parameters; ensure repeatability, reproducibility and reliability of the measurement system; measure critical process control parameters; organize data/information collected; approve the set of data/information organized through the stage-gate methodology;

- Perform phase A (Analyze), processing the data/information related to the process, based on the following tasks: analyze the set of data/information approved in phase M; update the product value stream map based on approved data/information; carry out value analysis of all activities that make up the business process to be improved; evaluate process flow/performance by identifying constraints to meet product demand; determine/validate root causes for critical restrictive resources identified in the process; approve set of root causes analyzed/validated through the stage-gate methodology;

- Perform Phase I (Enhance), making process improvements from corrective/preventive actions to block and eliminate root causes present in processes (increasing process performance), based on the following tasks: list the LSS (for products and/or processes already improved in Step 1) and Lean (for conventional QMS products and/or conventional processes) instruments that should be employed to address the root causes identified; elaborate value stream mapping for the future state; make necessary process changes using LSS and/or Lean Production toolset for process optimization according to the scope of the lean qua-

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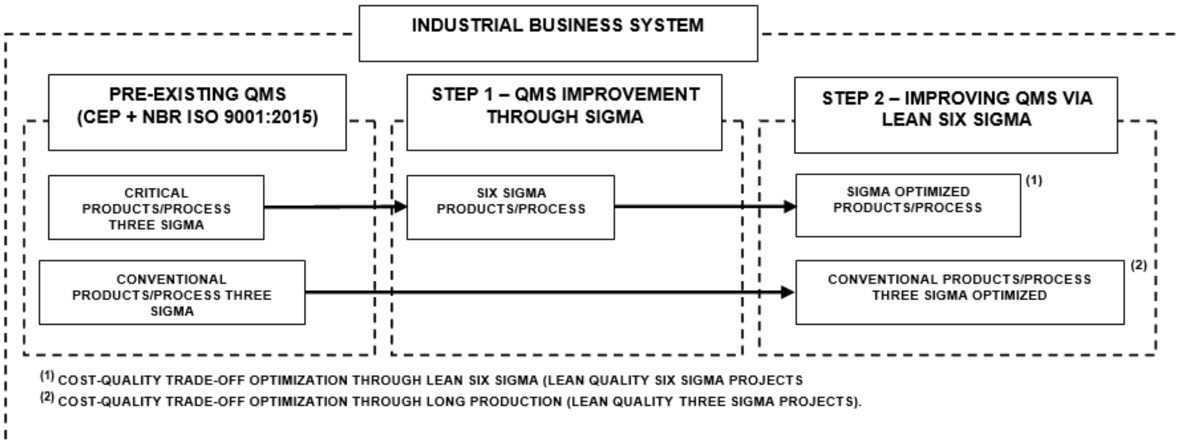

Figure 3. Logical structure of Step 2 (Improvement of the QMS via Lean Six Sigma).
Source: The author(s)

lity project; implement optimized solutions and verify results against project objectives/goals; prepare documentation of critical Six Sigma and/or conventional Three Sigma optimized processes; disseminate lean quality design improvements to other similar processes on a larger scale (continuous improvement cycle); approve the set of improvements made through the stage-gate methodology;

- Carry out phase C (Control), which presupposes the consolidation of process improvements, based on the following tasks: developing operational procedures and documented normative instructions for performing the activities that constitute the optimized processes (initial lean quality design and similar processes); Based on the procedures and normative instructions developed, perform functional training cycles to consolidate improvements obtained in the work routine; design control and traceability plans for optimized processes to enable the lean quality project manager (typically a Master Black Belt) to perform post-implementation monitoring of industrial scale improvements; perform follow-up of optimized processes to ensure performance based on new critical control parameter values; perform audits to verify the consolidation of improvements made to optimized processes; finalize lean quality project, calculating/documenting financial gains and communicating results to the top management of the industrial organization; approve the final report of the lean quality project through the stage-gate methodology.

Thus, Step 2 of the proposed referential model (Improvement of QMS via Lean Six Sigma) aims to prolong the longevity of the industrial quality system, and the costs associated with products and/or processes still need to improve the cost-quality trade-off to assist in the consolidation of the Industry 4.0 concept. Finally, the use of LSS to improve the quality system of small and medium industries, proposed through the execution of lean quality projects within the industrial business system, is fundamental to perpetuate total quality as a strategic weapon of indispensable competitive relevance.

5. CONCLUSION

Industrial competitiveness is linked to the proper understanding and management approach of the trade-off between cost, quality and innovation in products and processes, which, in this sense, depend on programs aimed at continuous improvement and the use of optimization models based on best industrial practices. Concern about building competitive advantages leads industries to constantly improve production system performance through projects aimed at optimizing quality management, in order to reduce operating costs and improve business performance. This allows maximizing the added value of goods and/or services through efforts to meet customer requirements.

Strategically, in small and medium-sized industries, improving organizational performance is dependent on continually improving quality management systems. In this sense, these industries are considered to be major promoters of economic development and income generating, and the power of competition is due to the accomplishment of projects to improve the quality of products and processes, favoring the practice of kaizen philosophy and contributing to improve the fulfillment of the final demand of products.

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Thus, consistent improvements in an already structured QMS enables the dynamics of organizational learning processes, as the realization of improvement projects stimulates a favorable environment for obtaining incremental innovations and setting standards of excellence. Thus, the research was mainly motivated by the difficulties that most Brazilian PMIs have regarding the optimization of their quality systems, taking into consideration a fundamentally important requirement for organizational growth and development: the formation of a corporate culture permanently focused on the pursuit of excellence in product and process performance.

The proposition of an "optimized script" to help small and medium-sized industries, aiming at step-by-step improvement of a quality system, is based on sequential sets of orientative activities along the lines of the reference model concept. Thus, Step 1, which was entitled "QMS Improvement via Six Sigma", sought to carry out projects to improve products and/or critical processes related to the pre-existing QMS, using the Six Sigma Program (which can be interpreted as an evolutionary strand of TQM) to introduce the Industry 4.0 concept and strengthen PMI competitiveness through an intense improvement cycle.

Step 2 was called "QMS Enhancement via Lean Six Sigma". The optimization of the cost/quality trade-off of products and/or processes was assumed through lean quality projects, combining Lean Production and Six Sigma, seeking to optimize the production system performance to increase innovation and further strengthen the concept of Industry 4.0. Industrial business system status is definitely achieved through lean quality projects, which are indispensable for the quality system maturity, further extending its "duration over time" and establishing total quality as the key structuring value to achieve excellence in strategic operations management.

Finally, as a suggestion for future works derived from the study, there are two possibilities that are complementary to each other. The first deals with a full and reliable application of the referential model in at least one PMI that already has a preliminary QMS structured through CEP and NBR ISO 9001: 2015, in order to perform its validation through research/action and narrative of the implementation through case study. However, the second perspective of future work concerns the additional validation of the proposed model by conducting a comprehensive multi-case study in at least three companies with properly structured quality systems; in addition, they are already carrying out advanced Six Sigma and LSS improvement projects. Thus, it is sought to evaluate the adherence of the proposed reference model compared to the understanding of the historical process of implementation of QMS present in these industrial organizations.

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