Integrating Six Sigma with ISO 9001

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Abstract

Purpose – By exploiting the relationships between Six Sigma and quality management systems (QMS) based on the ISO 9001 standard, this paper proposes a set of guidelines to combine and integrate both approaches in a systematic way. The guidelines are organised into integration topics, and each one is linked to the clauses of the ISO 9001 standard they refer to.

Design/methodology/approach – Based on the literature review, Six Sigma and QMS based on the ISO 9001 standard are thoroughly discussed and compared and beneficial synergies between them are identified. Based on this study, and to take advantage of the compatibilities and logical linkages between both approaches, guidelines for the integration of Six Sigma with the ISO 9001 requirements are developed.

Findings – Benefits resulting from the integration of Six Sigma with a QMS based on the ISO 9001 standard are mutual. The integration guidelines proposed in this paper provide a framework to unify process management practices, enhance the effectiveness of continual improvement efforts, facilitate the identification, evaluation and selection of Six Sigma projects, align the quality objectives defined for the QMS with Six Sigma project goals, establish relationships between the roles of a Six Sigma program and those inherent to an ISO 9001 QMS, and demonstrate how internal quality audits and management review benefit from a Six Sigma program.

Research limitations/implications – The integration models and guidelines herein proposed can be further expanded to include other relevant normative references, particularly environmental management systems (ISO 14001) and safety and health management systems (OHSAS 18001).

Originality/value – The set of guidelines proposed in this paper is original and will be of practical value to the increasing number of organisations adopting a process-model for the ISO 9001 standard, that seek to incorporate Six Sigma principles, practices, methods and tools within their QMS. The guidelines cover a wide spectrum of relevant activities that usually take place in the context of both initiatives. In addition, because each guideline is accompanied by the identification of the applicable clauses of ISO 9001, they provide a useful framework to develop, implement, maintain, and improve a QMS in parallel with a Six Sigma program.

Keywords ISO 9001, Quality management systems (QMS), Six Sigma, Quality management, Quality management techniques, ISO 9000 series

Paper type Conceptual paper

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1. Introduction

Since they were introduced, back in the late eighties, the popularity of quality management systems (QMS) based on the ISO 9000 standards has widely grown around the world. According to the successive annual ISO Surveys, the number of certified ISO 9001 organisations has increased, year after year, reaching a total of at least 1,109,905 certificates in 178 countries by the end of 2010, more than the double of the number recorded at the end of the year 2000, of 457,834 certificates (ISO, 2011). Since the revision occurred in 2000, the ISO 9001 standard is based upon a process-model, according to which all the activities that impact customer (and not only the product) requirements, should be identified, mapped, understood, controlled and continuously improved (ISO, 2005, 2008).

Six Sigma is also a process-focused approach aimed at achieving business improvement. The main goal here is to improve the performance of a specific core process, one project at a time. To that end, it is important to understand not only the processes, by themselves, but also how their outputs impact on the customer's (both external and internal) requirements.

By exploring compatibilities between Six Sigma and ISO 9001 QMS, this paper discusses how both approaches may be successfully combined and what benefits may arise from their integration. For that purpose, a set of guidelines is presented and discussed.

The paper starts by reviewing the relevant literature concerning the combination and/or integration of Six Sigma and ISO 9001. In Section 3, both approaches are compared and beneficial synergies among them are identified and detailed, while in Section 4 a set of organised and comprehensive guidelines to systematically integrate the ISO 9001 framework with Six Sigma is proposed and discussed.

2. Literature review

The literature review is presented in three subsections. The first two subsections describe key concepts of both ISO 9001 QMS and Six Sigma approaches, along with their major benefits and limitations. The third subsection reviews the status of research proposals for combining or integrating them.

2.1 Six Sigma

Since Motorola's first proposed it during the mid-1980s, Six Sigma has gained increasing interest, both from the scientific and business communities. It is not easy to define Six Sigma in one simple sentence (Caulcutt, 2001) since it can be defined in a variety of ways (Schroeder *et al.*, 2007). For this reason, McCarty *et al.* (2004) states that to understand Six Sigma, one should view it according to the following three perspectives:

(1) management system;

(2) methodology; and

(3) metric.

Harry and Schroeder (2000), Kwak and Anbari (2006), Snee and Hoerl (2005) and Brue and Howes (2006) categorise the Six Sigma concept in three similar levels.

Metric perspective. Six Sigma can be seen as a statistical measure of process performance. In the field of statistics, sigma (σ) is a Greek letter that usually represents

standard deviation, which is a measure of variation. The focus of Six Sigma is reducing variability in critical to quality (CTQ) characteristics around specified target values to the level at which failure or defects are extremely unlikely (Montgomery and Woodall, 2008). Figure 1 shows the statistical concept behind Six Sigma for a process with two-side specification limits, under the assumption of a measurable and normally distributed CTQ characteristic.

A process with a Six Sigma level of performance is at a distance of six standard deviations (6σ) from both specification limits when the value of its mean equals the target value. In this case, the number of defects will be of about 0.00189 parts per million (ppm), so that it can be stated as being an almost defect free process. In the long term, such a process is robust enough so that it can also accommodate shifts of up to $\pm 1.5\sigma$ in its central tendency location around the target value, because the measured CTQ characteristic will not fall out of specification limits, even if that happens, more than 3.4 times over each million of opportunities.

Not every process needs to operate at a Six Sigma level, since the established quality level of performance depends on its strategic importance and the cost of improvement relative to its benefit (Kumar *et al.*, 2007).

Methodology perspective. Six Sigma is a systematic, highly disciplined, customer-centric and profit-driven organisation-wide strategic business improvement initiative (Tang *et al.*, 2007) that is based on a project-by-project approach (Bendell, 2006). Six Sigma projects are selected to be in line with the business goals and strategy (Gijo and Rao, 2005), and executed through a well defined sequence of phases, using appropriate tools and techniques in each of them. Between each transition of phase, a formal project review, called "tollgate", takes place (Montgomery and Woodall, 2008). There are two main methodological approaches, whose steps build on the PDCA cycle (Jones *et al.*, 2010), through which Six Sigma teams carry out their projects:

(1) *DMAIC, standing for define-measure-analyse-improve-control.* This roadmap intends to improve the capability of a process in a certain CTQ characteristic. The main idea is to minimize variability over the most significant inputs of the process, with regard to the desired output, in order to optimise the performance over the CTQ characteristic.

(2) *Design for Six Sigma (DFSS).* This approach is used not to improve an existing process, but rather to redesign or reengineer it, as well as to design a new one.

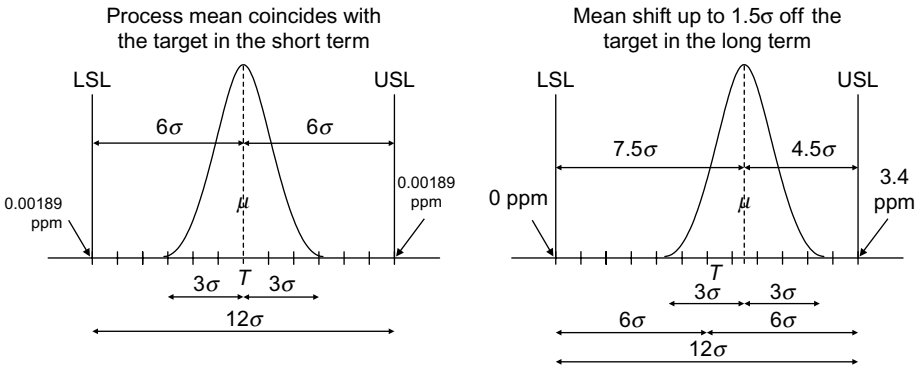


Figure 1.
Statistical concept behind Six Sigma

DFSS can also be employed to design or redesign new products/services. Unlike the DMAIC methodology, the phases or steps of DFSS are not universally recognised or defined (Chang and Su, 2007). The acronyms identify-design-optimise-validate (IDOV) and define-measure-analyse-design- verify (DMADV) are amongst the roadmaps most usually proposed in order to conduct a DFSS project. However, despite the variety of acronyms, all DFSS versions share fundamental strategies, sets of tools and deliverables (Shahin, 2008).

Management system perspective. Six Sigma builds on leadership to become an organisation wide initiative. By the hand of leaders such as Bob Galvin, of Motorola, or Jack Welch, of GE, among others, many organisations successfully implemented a Six Sigma system directly linked to their business strategy, involving all of the organisation in a broad implementation scope. Therefore, it is when Six Sigma is articulated with the strategic activities that organisations see its greatest impact on business results (McCarty *et al.*, 2004). Only by prioritizing and selecting projects that contribute the most to organisation's business performance, can management ensure significant gains from the Six Sigma initiative (Watson, 2004).

In order to effectively develop and sustain a Six Sigma system, there are a set of critical factors that must be recognised as contributing to the success of the initiative within an organisation. A global and wide deployment of a Six Sigma program demands the existence of an appropriate role structure with specific levels of responsibilities, knowledge and qualification (Zu *et al.*, 2008). This structure, usually known as "belt system" (Park, 2003), is shown in Figure 2. Antony and Bañuelas (2002) and Brady and Allen (2006) identified and thoroughly discussed a set of other critical success factors for Six Sigma implementation.

2.2 QMS based on the ISO 9000 family of standards

ISO 9000 corresponds to a family of international standards whose main aim is to assist organisations in implementing and operating effective quality systems (Hoyle, 2001).

Inspired on the BS5750 series of quality assurance system standards developed by the British Standards Institution, back in 1979 (Brown *et al.*, 1998), the first set of ISO 9000 standards first emerged in 1987 as the torch-bearer of the standards for doing business in Europe (Martínez-Costa *et al.*, 2009). As a result, they have stimulated third-party audits and certification world-wide (Van der Wiele *et al.*, 2000). Their popularity grew significantly during the 1990s, first in the manufacturing sectors and in Europe (Guler *et al.*, 2002), but later on in all kinds of organisations and countries (Lee *et al.*, 2009).

It requires organisations to identify, classify and map their key processes, and to establish their mutual relationships, normally through a net of interlinked processes (Tsim *et al.*, 2002). Control and continual improvement activities, for those processes, must also be defined, as well as the responsibilities for process management (usually a process owner) and implementation. Measurable key performance indicators (KPIs) are established to evaluate their levels of effectiveness and efficiency, and to monitor their evolution against assumed targets.

2.3 Integration of Six Sigma with ISO 9001 QMS

The successful implementation of a Six Sigma program depends on how effectively a company is able to articulate it with its existing management systems (Hahn, 2005; Salah *et al.*, 2010), particularly with its QMS (Pfeifer *et al.*, 2004).

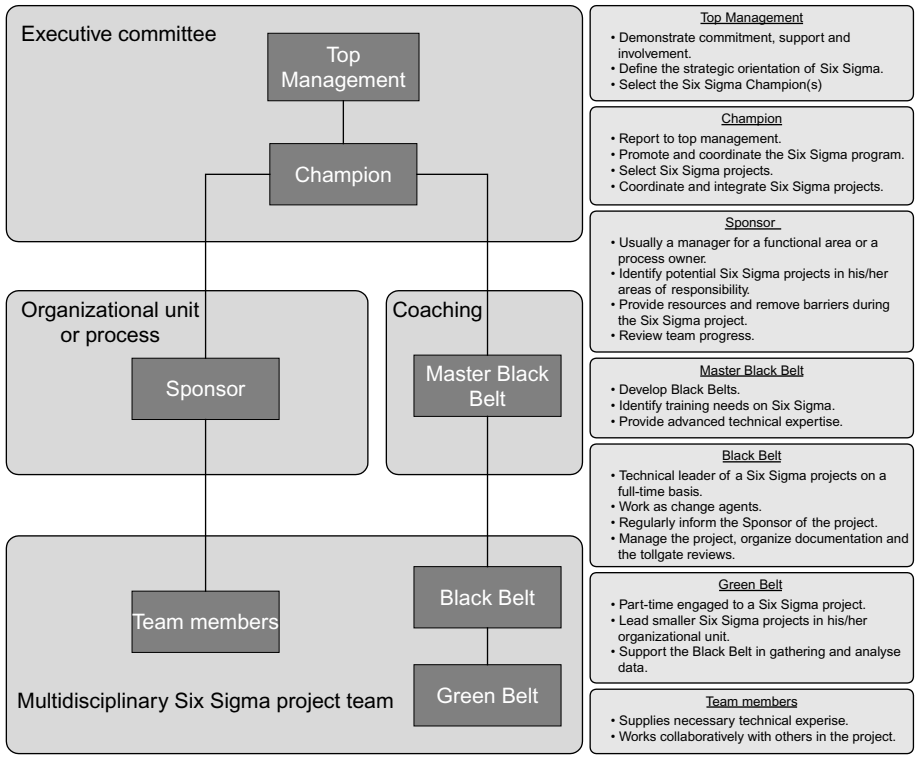


Figure 2.
General human structure of a Six Sigma program and its roles

Since both approaches often need to coexist, the development of linkages to articulate them assumes high relevance. According to Wessel and Burcher (2004), the exploitation of such synergies is even more important for small- and medium-sized enterprises. The integration of Six Sigma with ISO 9001 QMS is one of the emerging research trends on the Six Sigma subject (Antony *et al.*, 2006; Nonthaleerak and Hendry, 2006; Kwak and Anbari, 2006; Kumar *et al.*, 2008).

Although Six Sigma and ISO 9001 are both important and required, sharing many principles (Bewoor and Pawar, 2010; Watson, 2004), they actually serve different purposes (Snee and Hoerl, 2003; Park, 2003). Our analysis of the literature enabled us to identify relevant differences between both approaches, when attending to a set of parameters, as exhibited in Table I.

There are logical linkages between Six Sigma and ISO 9001 (Snee and Hoerl, 2003) and resulting advantages from their integration (Van den Heuvel *et al.*, 2005). Undertaking a Six Sigma initiative can help an organisation to optimise the efficiency and effectiveness of its business processes (Gupta, 2004; Basu and Wright, 2003; Hrgarek and Bowers, 2009), and to make progress toward achieving an ISO 9001 certification (Watson, 2004). On the other hand, the ISO 9000 family of standards paves the way for Six Sigma deployment (Kubiak, 2003), providing a useful reference for those involved in Six Sigma activities (Truscott, 2003; Buell and Turnipspeed, 2003). A set of researchers have identified specific linkages between Six Sigma and ISO 9001, as we discuss in the following points:

Parameter	ISO 9001:2008	Six Sigma
Framework	A framework to create "improvement thinking"	A framework to achieve improvement and to link it to profitability
Purpose	Provides an equitable basis for assessing how organisations can effectively meet customer and applicable regulatory requirements	Achieves sustainable business growth and profitability by improving and/or innovating processes, products and services that maximize the value delivered to the customers
Intent	It is used for contractual, certification and/or assessment purposes	It is used to optimise performance and maximize profitability
Scope	Defines the requirements for a QMS	Makes use of a set of strategies, methodologies, tools and metrics to improve business performance
Leadership	Management responsibility is promoted by the establishment and communication of the quality policy and through management review activities	Requires leadership to aim at highest performance with highest profitability, creating an organisational structure which pursues the objectives
Improvement method	PDCA model	DMAIC or a DFSS roadmap, which are extensions of PDCA
Techniques/ tools	Does not specify	Specified toolbox
Responsibilities	Specifies the functions and the responsibilities of the process owner and the management representative (responsible for QMS), and states that the responsibilities for all the functions within the QMS should be defined	Defines specific functions and responsibilities, such as: Champion, Sponsor, Process Owner, Master Black Belt, Black Belt, and Green Belt
Education	Requires that personnel have appropriate education, training, skills, and experience to do his/her job, meaning such qualification criteria should be established	Defines qualification requirements for the belt infrastructure (e.g. Black Belt, Green Belt), and recognises that in all the areas of an organisation, the levels of qualification depends on the functional and processes requirements
Financial benefits	Benefits of implementation have been reported, including financial benefits, but in general they were not quantified	Many companies have reported and quantified large amounts of savings due to the initiative
Documentation	Six specifically defined documented procedures	Documentation is not specified
Major limitations	There are no direct requirements concerning profitability, strategy, and financial topics	Requires data to be available. Some statistical assumptions, especially the 1, 5σ shift in the long term, lack better theoretical justification

Table I.
Differences between ISO 9001:2008 and Six Sigma

- *Both approaches have a focus on continual improvement activities.* Six Sigma DMAIC is inspired on the PDCA continual improvement cycle (Klefsjö *et al.*, 2006), so the DMAIC method can actually be used to fulfil the continual improvement part of the standard's requirements (Gupta, 2004). Together, the process model, the eight principles and the requirements of ISO 9001 provide a comprehensive and useful framework to create opportunities improvement; however, an ISO 9001 QMS needs a systematic and structured continual improvement process, such as Six Sigma. In this sense, Six Sigma projects become one of the ways

through which continual improvement takes place in an organisation (Warnack, 2003). Bewoor and Pawar (2010) developed a micro/operational level analysis to facilitate the implementation of the DMAIC roadmap phases as part of an organisation's ISO 9001 QMS. They mapped the Six Sigma DMAIC phases to the clauses of the ISO 9001 standard, as presented in Table II.

- *ISO 9001 requirements concur to the identification of potential Six Sigma projects.* Bewoor and Pawar (2010) and Pfeifer *et al.* (2004) state that QMS audits can act as a source of information to identify potential improvement areas. In addition to this, Dey (2002) refers that Six Sigma projects can be identified by analysing customer requirements and satisfaction measures determined within the ISO 9001 QMS.
- *Business process management principles are adopted by both approaches.* ISO 9001 QMS and Six Sigma share a core focus on measuring, improving, and rationalising organisational processes (Benner and Tushman, 2001). ISO 9001 states that companies shall identify, map and continuously improve their key processes (Biazzo and Bernardi, 2003), while Six Sigma requires the creation and analysis of a process mapping model at the beginning of a project, usually using a supplier, input, process, output, customer (SIPOC) diagram (Conger, 2010). This means that an ISO 9001 QMS often provides an input to construct a SIPOC diagram (Pfeifer *et al.*, 2004). Moreover, Gupta (2004), in the context of his Six Sigma Business Scorecard models, indicated a complete set of typical key business processes for companies to consider, that provide a useful guide for the identification of key processes under the context of an ISO 9001 QMS.
- *Both approaches recognise business processes as an interlinked system.* The systems approach to management of ISO 9001 underlines that, after identifying the key business processes, an organisation should establish the relationships between them. Successful Six Sigma projects recognise that processes are connected in an interdependent system (Dey, 2002), so that the network of processes established in the context of the ISO 9001 QMS provide useful information when Six Sigma project teams analyse process interactions (Pfeifer *et al.*, 2004).
- *Alignment between quality objectives and Six Sigma project goals.* It is important that continual improvement initiatives like Six Sigma are aligned with the organisational objectives and targets (Pojasek, 2008). Process objectives defined in the QMS can actually be compared with the planned objectives for a Six Sigma project (Bewoor and Pawar, 2010). In this sense, the Six Sigma program can have a positive impact on processes and customer requirements (Warnack, 2003), concurring to enhance the effectiveness and/or efficiency of the ISO 9001 QMS.

Table II.
Mapping of the DMAIC roadmap phases with the ISO 9001:2008 clauses

DMAIC roadmap phases	ISO 9001:2008 clauses
Define	7.1.3.2 (ISO 9004:2000 clause), 8.4
Measure	8.2.1, 8.2.3, 8.2.4
Analyse	6.2.2, 8.4
Improve	5.1, 8.1.C, 8.5.1
Control	4.1.C, 4.1.D, 4.2, 7.5.1, 7.5.4, 7.6

Source: Adapted from Bewoor and Pawar (2010)

- *Linkages between ISO 9001 human resources management and the human structure of a Six Sigma program.* Human resources management procedures, defined in the context of a QMS, support the implementation of the human structure of a Six Sigma program (Snee and Hoerl, 2003). Since the roles, responsibilities and required competencies for the personnel involved in the ISO 9001 QMS need to be defined, such information can be used to choose the most capable participants in a Six Sigma project (Bewoor and Pawar, 2010). In addition, the ISO 9001 human resources management requirements permit not only that available qualified personnel to lead Six Sigma projects are identified, but also that training needs for the personnel involved in the Six Sigma program are determined by comparing the function-specific required knowledge with the available qualification (Pfeifer *et al.*, 2004).
- *Interfaces between the quality management review process and the Six Sigma program.* Senior management's strong commitment, support, and leadership are essential to Six Sigma implementation (Kwak and Anbari, 2006). The Six Sigma program takes direction from the senior management, so it can interact closely with the ISO 9001 management review (Warnack, 2003). In this sense, management review activities can include reviews of the overall Six Sigma program and recommendations on ways to continually improve the program itself (Lupan *et al.*, 2005).
- *Six Sigma can assist an organisation in identifying tools and techniques that can be useful to the development, implementation, maintenance and improvement of its ISO 9001 QMS.* Lupan *et al.* (2005) underline the importance that the structured use of Six Sigma tools and techniques has in managing the whole QMS by facts. Pfeifer *et al.* (2004) suggest the use of SIPOC diagrams to fulfil a set of specific ISO 9001 process management requirements. Gupta (2004) recommend the use of Six Sigma statistical tools to fulfil the data analysis requirements included in the standard.
- *ISO 9001 internal audits can be performed in parallel with Six Sigma DMAIC projects.* An ISO 9001 QMS can help to sustain the gains of Six Sigma projects (Dey, 2002). In this sense, internal audit programs can be expanded to include not only administrative features of the Six Sigma initiative, but also individual control phase and closed projects (Warnack, 2003).
- *Documentation produced by both ISO 9001 QMS and Six Sigma allows for the systematisation and standardisation of improvement activities.* According to Snee and Hoerl (2003), ISO 9001 is an excellent vehicle for documenting and maintaining the process management systems involving Six Sigma. The ISO 9001 QMS documentation can make references to the Six Sigma program in order to increase its systematisation and effectiveness (Warnack, 2003), while the documentation produced during the Six Sigma projects can source the QMS for its continual improvement (Bewoor and Pawar, 2010).
- *Linkages between Six Sigma and an ISO 9001 QMS can benefit the cultural environment of an organisation.* Based on the experience obtained from two ISO 9001 certified secondary schools in Hong Kong, Yeung (2007) concludes that integrating customer requirements and the standard's clauses into a Six Sigma program can have a positive effect over an organisational cultural environment.

3. Proposed guidelines to systematically integrate Six Sigma with ISO 9001 QMS

In this section, guidelines to systematically exploit synergies between Six Sigma and QMS, based on the versions published in 2000 and 2008 of the ISO 9001 standard, are developed and discussed. A set of 27 integration guidelines is proposed and linked to the clauses of ISO 9001. The guidelines are organised according to the following six topics, related to the common elements of the ISO Guide 72:2001:

(1) policy;
(2) planning;
(3) implementation and control;
(4) performance assessment;
(5) improvement; and
(6) management review.

Guidelines for "policy"

Both initiatives, ISO 9001 QMS and Six Sigma, to be successfully implemented require a clear support and commitment from an organisation top management. Requirements under the Section 5 of ISO 9001, especially those included in clause 5.1, make mention to a set of practices for top managers to demonstrate their commitment in implementing, maintaining, and improving the QMS. Those practices can be adopted and extended to also include the Six Sigma program.

For this first topic, the following integration guidelines can be formulated:

(1) *Guideline 1.* Top management commitment to the Six Sigma program, as well as to its integration with the ISO 9001 QMS, can be stated in the quality policy.
Applicable ISO 9001 clauses: 5.1, 5.3.

(2) *Guideline 2.* Top management can demonstrate their commitment to the Six Sigma program, by:
- Leading management reviews that include review of the program itself.
- By providing training, resources and an appropriate human infrastructure to support the development of Six Sigma projects.
- Communicating its purpose, role within the QMS, and its importance to meet business goals.

Applicable ISO 9001 clauses: 5.1.

Guidelines for "planning"

By analysing clause 4.1 of the ISO 9001 standard, it is possible to identify six required steps in order to develop a QMS based on both process approach and system approach to management principles:

(1) Identify and map key processes.
(2) Determine the relationship between those key processes.
(3) Define criteria and methods to ensure and effective operation and control of the processes.

(4) Allocate the necessary resources and ensure the availability of the necessary information to properly run the processes.

(5) Monitor, measure and analyse those processes to assess their effectiveness and efficiency.

(6) Develop and implement corrective and preventive actions in order to continuously improve key processes.

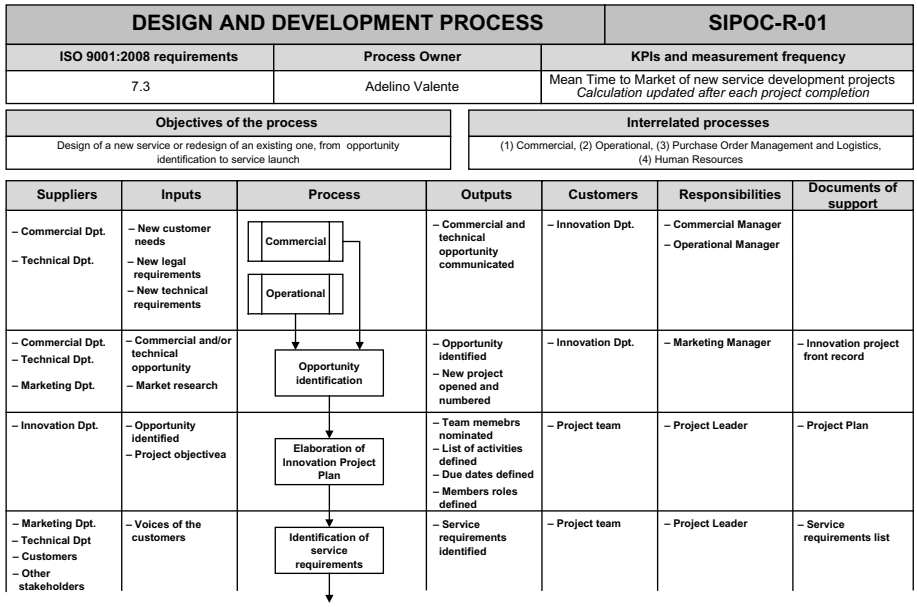
ISO 9001 highlights the importance of the systematic identification and management of the processes employed within an organisation (Biazzo and Bernardi, 2003), while Six Sigma is also a process-focused approach to business improvement (Yang and El-Haik, 2003). Therefore, logical linkages in this field might be exploited, as described by the following guidelines:

- *Guideline 3.* SIPOC diagrams, a Six Sigma process mapping tool, can be used to capture the sequence of activities inherent to each key process of the ISO 9001 QMS. The use of the same process mapping approach in both initiatives facilitates the adoption of common procedures and of a single language. Each SIPOC diagram can eventually be incorporated into a broader process description model, containing additional information required by ISO 9001 (e.g. process objectives, responsibilities, KPIs to measure the process effectiveness and efficiency, applicable ISO 9001 clauses).
  Applicable ISO 9001 clauses: 4.1, 7.1, 7.3.1, 7.4.1, 7.5.1.
- *Guideline 4.* The relationship of a certain process of the QMS with other organisational processes can also be described in a SIPOC diagram format.
  Applicable ISO 9001 clauses: 4.1, 7.1, 7.3.1, 7.4.1, 7.5.1.
- *Guideline 5.* System diagrams, a model often employed in Six Sigma projects to visually capture the dynamic interactions between the components of a process or between different processes of a system, can be used within the regular process management activities performed in the context of an ISO 9001 QMS. Two main benefits might arise from such use: to better understand the relationships between the key processes of the QMS, and to understand how improvement actions in one single process positively or negatively affects the whole ISO 9001 QMS.
  Applicable ISO 9001 clauses: 4.1, 7.3.1, 7.4.1, 7.5.1, 8.1.

The layout reported in Figure 3, or similar ones, provides an example of how SIPOC diagrams can be used in the context of guidelines 3 and 4.

Quality objectives are those results that the organisation needs to achieve in order to improve its ability to meet the needs and expectations of all the interested parties (Hoyle, 2003). Clause 5.4.1 of ISO 9001 requires that specific, measurable, achievable, realistic and time-bounded objectives are set at all relevant functions and levels of the organisation. Quality objectives need to be consistent with the quality policy defined by top management and must include goals directly related to the products and services provided by the organisation.

According to Truscott (2003), it is of vital importance that Six Sigma projects are chosen so that they are specifically directed at the achievement of business objectives, which include the quality objectives. In addition to this, goals and milestones



DESIGN AND DEVELOPMENT PROCESS		SIPOC-R-01
ISO 9001:2008 requirements	**Process Owner**	**KPIs and measurement frequency**
7.3	Adelino Valente	Mean Time to Market of new service development projects *Calculation updated after each project completion*

Objectives of the process	**Interrelated processes**
Design of a new service or redesign of an existing one, from opportunity identification to service launch	(1) Commercial, (2) Operational, (3) Purchase Order Management and Logistics, (4) Human Resources

Suppliers	Inputs	Process	Outputs	Customers	Responsibilities	Documents of support
– Commercial Dpt. – Technical Dpt.	– New customer needs – New legal requirements – New technical requirements	Commercial Operational	– Commercial and technical opportunity communicated	– Innovation Dpt.	– Commercial Manager – Operational Manager	
– Commercial Dpt. – Technical Dpt. – Marketing Dpt.	– Commercial and/or technical opportunity – Market research	Opportunity identification	– Opportunity identified – New project opened and numbered	– Innovation Dpt.	– Marketing Manager	– Innovation project front record
– Innovation Dpt.	– Opportunity identified – Project objectivea	Elaboration of Innovation Project Plan	– Team memebrs nominated – List of activities defined – Due dates defined – Members roles defined	– Project team	– Project Leader	– Project Plan
– Marketing Dpt. – Technical Dpt – Customers – Other stakeholders	– Voices of the customers	Identification of service requirements	– Service requirements identified	– Project team	– Project Leader	– Service requirements list

Figure 3.
Example of a process mapping using a SIPOC diagram that is incorporated into a broader process description used in the context of an ISO 9001:2008 QMS

established in the planning phase of a Six Sigma project should be aligned and coherent with the organisation's objectives.

For this type of synergies, the following integration guidelines can be stated:

- *Guideline 6.* The analysis of existing gaps between the established quality objectives and the results that are actually obtained (measured through the use of KPIs) provides useful information to identify potential Six Sigma projects.

  Applicable ISO 9001 clauses: 5.4.1, 5.4.2, 8.2.3.

- *Guideline 7.* To increase the effectiveness of the Six Sigma project selection process, the extent to which each potential project contributes to the achievement of the established quality objectives shall be considered. This also allows that improvement efforts, developed under the Six Sigma program, are directed to the areas for improvement with most impact over the ISO 9001:2008 QMS.

  Applicable ISO 9001 clauses: 5.4.1, 5.4.2.

- *Guideline 8.* The quality objectives established for the ISO 9001:2008 QMS help teams to define more reliable goals and milestones when planning their Six Sigma project. On the other hand, the performance improvements achieved after the completion of a Six Sigma project, together with the lessons learned, provide relevant input information to review the need to update the quality objectives established for the QMS.

  Applicable ISO 9001 clauses: 5.4.1, 5.4.2, 5.6.

Guidelines for "implementation and control"

The Deming/Shewhart PDCA cycle is a model for learning and improvement that underlies Six Sigma provides an efficient manpower cultivation and utilization, by employing a "belt system" (Park, 2003) with clearly defined roles and responsibilities

(Lunau *et al.*, 2008). Appropriate training must be provided to the personnel and executives involved in the Six Sigma program. Although standard training curricula exist for the main Six Sigma roles, such as those provided by the America Society for Quality or the Motorola University, Six Sigma training is often customized to fulfil the specific needs of an organisation (Hahn, 2005). In addition, the definition of criteria to select the best candidates for each role within the belt structure, particularly for the Black Belt role, is crucial to the development of a Six Sigma initiative (Ingle and Roe, 2001).

According to clause 5.5.2 of ISO 9001, top management should assign a member of the management staff to act as the organisation's management representative for the QMS. That person shall directly report to the organisation's top management, and have the authority and responsibility to ensure that the QMS is working properly. Another role inherent to an ISO 9001 QMS, but not explicitly required in the standard, is that of the process owner. According to Smart *et al.* (2009), the identification of process owners and their allocation to key processes are critical elements of a business management system based on the process approach principle. A process owner is a manager responsible for process performance and in working at the interfaces with other key processes.

Clause 6.2 of ISO 9001 covers the specific requirements for management of human resources. Subclause 6.2.1 requires that the necessary education, training and skills of the personnel performing work, that directly and indirectly affect the quality of the product (i.e. the personnel involved in the activities of the QMS), are established. Subclause 6.2.2 states that employees need to be aware of the relevance and importance of their activities within the QMS and how they contribute to the achievement of the quality objectives. Subclause 6.2.2 also requires that employees' competency and training needs are determined and addressed, and that the effectiveness of the training, that was provided, is assessed.

The following integration guidelines can be formulated:

- *Guideline 9.* A key role of a Champion is to guide the overall Six Sigma program. The Champion is usually a member that belongs or reports to the organisation's top management. Therefore, the Six Sigma Champion and the management representative for the QMS share similar roles and responsibilities, so both functions can be assigned to one same person.

  Applicable ISO 9001 clauses: 5.5.2.

- *Guideline 10.* Process owners and organisational units' managers can act as Sponsors, sometimes called Project Champions, under the Six Sigma human structure. The main role of a Sponsor is to help in the identification, initiation, and coordination of Six Sigma projects in their areas of responsibility.

  Applicable ISO 9001 clauses: 5.2.2.

- *Guideline 11.* To completely integrate a Six Sigma program with an ISO 9001:2008 QMS, it is necessary to determine the appropriate levels of qualification, skills and experience, for all the roles that are part of the Six Sigma human structure, including the Champion, Sponsor, Master Black Belt, Black Belt, and Green Belt. The organisation needs to ensure and demonstrate that the personnel assigned to those roles have the required competency.

  Applicable ISO 9001 clauses: 6.2.1, 6.2.2.

- *Guideline 12.* Similarly to the personnel involved in the other activities of the ISO 9001 QMS, in an integrated approach it is necessary to identify the training needs

of the people that participate in the Six Sigma program. The training needs typically fall in the areas of the Six Sigma tools, techniques, methods and principles. The evaluation of the training effectiveness, after it was provided, also shall to be performed when Six Sigma is integrated with an ISO 9001 QMS. The responsibility of these activities is usually assigned to a Master Black Belt.

Applicable ISO 9001 clauses: 6.2.2.

- *Guideline 13.* By comparing the available levels of education, training, skills and experience of the personnel with required levels for each of the roles under the Six Sigma program, it is easier to perform the following activities: identify Black Belt and Green Belt candidates, determine training needs for all the employees involved in the Six Sigma program, and choose the most capable personnel to participate in Six Sigma projects.

  Applicable ISO 9001 clauses: 6.2.1, 6.2.2.

Subclauses 4.2.3 and 4.2.4, respectively, state that written procedures to control the QMS documents (both generated internally and externally) and records shall be established. Those rules can be used as a support for the Six Sigma program, as suggested by the following guidelines:

- *Guideline 14.* The written procedures describing the rules to control the use of documents and records under the ISO 9001 QMS, can be used as procedure rules to manage the large amounts of documents and records often produced during the planning, execution and completion of a Six Sigma project, respective tollgate reviews and post-project activities.

  Applicable ISO 9001 clauses: 4.2.3, 4.2.4.

- *Guideline 15.* After a Six Sigma project is completed, a post-project evaluation shall be conducted to measure the success of the project regarding its original and modified objectives. This evaluation usually contains explanations of major variances, lessons learnt from the project, and recommendations to support the management of future projects. The information produced by these activities is of crucial importance for the knowledge of the organisation. Therefore, the existence of an effective ISO 9001 procedure to control the documentation containing such information is imperative.

  Applicable ISO 9001 clauses: 8.2.2.

Guidelines for "performance assessment"

Clause 8.4 of ISO 9001 underlines the importance of analysing factual data to assess the suitability and effectiveness of the QMS, as well as to identify opportunities for improvement. However, such data is only valuable if it is analysed. Table III indicates and categorises several sources of data that can be useful in the context of an ISO 9001 QMS.

Data can be gathered from retroactive/historical sources, which can be either internal or external. From an ISO 9001 perspective, the latter provides not only customer-related data such as customer satisfaction measures, customer complaints, or indicators on conformance to customer requirements, but also information about how suppliers are actually performing. Internal sources include, among others, results of KPIs regarding product conformity and processes efficiency and capability.

IDOV phases description (Antony, 2002)	IDOV	PDCA	PDCA phases description (Moen and Norman, 2009)
Identify customers and their requirements Define design requirements for the product, service or process Identify customer critical to quality characteristics (CTQs) Plan of functional and engineering requirements Determine the relationship between customer and technical requirements Determine the target for each CTQ	*I*dentify	*P*lan	Plan a change or test, aimed at improvement
Analyse design requirements and key design parameters, and their relationship with CTQs Identify design alternatives Utilise concurrent engineering practice Study the relation of design parameters to CTQs at sublevels in complex processes or systems Identify of the risks involved and typical failures	*D*esign	*D*o	Carry out the change or test, preferably on a small scale
Identify sources of variability Minimise product performance sensitivity to all sources of variation Apply tolerance design for critical design parameters Optimise the design for manufacturability Optimise the design for product reliability Determine design capability and comparison with design specifications	*O*ptimise	*C*heck	Check/study the results. What did we learn? What are the results?
Verify the design to ensure that it meets the set requirements Assess performance, reliability, capability, etc Develop process control plan for the mean and variance of CTQs in production Develop a DFSS scoring card	*V*alidate	*A*ct	Adopt the change or abandon it, or run through the cycle again

Table III.
IDOV roadmap phases compared with the PDCA cycle

In addition to historical data, it is also important to gather and analyse data from more proactive sources that can also be classified as internal and external. Data and information provided by benchmarking studies, market research evaluations, among others, are useful to assess products and processes trends, determine latent and unstated customer needs.

By analysing relevant and factual data with origin in such sources, the degree of effectiveness of the QMS can be evaluated, the achievement of quality objectives can be verified, the study of how well customer, statutory and regulatory requirements are

identified and satisfied can be performed, the efficiency of key processes can be assessed, and a set of other areas for improvement can actually be identified and prioritised, leading to the identification of potential Six Sigma projects that, if completed successfully, contribute to the continual improvement of the QMS.

On the other hand, according to ISO/TR 10017:2003, statistical techniques allow for a better use of the available data to assist in decision making. Six Sigma makes use of advanced data analysis tools (Kwak and Anbari, 2006) in a structured way, thus providing a powerful framework to analyse quantitative data. In addition, the Six Sigma toolset also provides techniques and tools to deal with qualitative data and information (Pyzdek, 2003; ISO, 2003).

The following integration guidelines can be stated for this topic:

- *Guideline 16.* The analysis of data and information with origin in internal and external sources, collected in a retroactive and proactive way, is useful in the context of an ISO 9001 QMS and of a Six Sigma program. It supports the activities related to the measurement, monitoring and improvement of the effectiveness and efficiency of the QMS, and also assists the Six Sigma Sponsors in the identification of potential Six Sigma projects by detecting areas for improvement and innovation opportunities. Areas for improvement usually result in Six Sigma DMAIC projects, whereas innovation opportunities in DFSS projects.

  Applicable ISO 9001 clauses: 8.4.

- *Guideline 17.* The tools and techniques incorporated within the Six Sigma DMAIC and DFSS frameworks improve the ability of gathering and analysing quantitative and qualitative data inherent to the activities of an ISO 9001 QMS. Those activities include, but are not limited to: assess the effectiveness of training actions, determine and review requirements related to the product, verify if design outputs satisfy all the input requirements, verify if purchased product conforms with specified purchased requirements, monitor and control product and service activity, control and validate processes that cannot be readily measured, ensure that measuring and monitoring processes and equipments are adequate, monitor and analyse information about customer perception, report internal audit data, measure, monitor and control data from key-processes and products and analyse if quality objectives are being achieved, control nonconforming product, identify root-causes of problems in order to develop corrective and/or preventive actions.

  Applicable ISO 9001 clauses: 6.2, 7.2.1., 7.2.2, 7.4, 7.5.1, 7.5.2, 7.6, 8.2.1, 8.2.2, 8.2.3, 8.2.4, 8.3, 8.5.2, 8.5.3.

According to ISO 19011:2002, an audit is a systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled. Since audit conclusions are based on evidences, it means that the auditing process relies on the factual approach principle, also a key feature of Six Sigma (ISO, 2002).

An audit can scope the whole ISO 9001 QMS, or just a part of it (e.g. a process, a set of processes, an activity, a procedure, an organisational unit). An internal audit, also known as first-party audit, is conducted by, or on behalf of, the organisation itself and can be a useful instrument in the context of the Six Sigma initiative.

The following integration guidelines regarding this topic can be stated:

- *Guideline 18*. The conclusions of internal audits indicate opportunities for improvements and nonconformities that can be resolved through the initiation, development and completion of one or more Six Sigma projects.
  Applicable ISO 9001 clauses: 8.2.2.
- *Guideline 19*. Internal audits can be useful during the "control" phase of the DMAIC roadmap, in order to help to sustain the gains achieved at the end of the "improvement" phase. Internal audits can also target closed Six Sigma projects to assess if their objectives were achieved.
  Applicable ISO 9001 clauses: 8.2.2.
- *Guideline 20*. Internal audits programmes can be expanded to include audits to the Six Sigma program itself, in order to evaluate to which extent the initiative is meeting the intended objectives.
  Applicable ISO 9001 clauses: 8.2.2.

Six Sigma provide a wide set of metrics that can be used to assess both process and product performance. In this sense, the following guideline can be stated:

- *Guideline 21*. Six Sigma metrics, particularly the sigma level, the number of defects per million of opportunities (DPMO), the rolled throughput yield (RTY), among others, can be used to measure QMS processes performance and/or the characteristics of the products, to verify if customer and product requirements have been met, as stated in ISO 9001.
  Applicable ISO 9001 clauses: 8.2.3, 8.2.4.

Guidelines for "improvement"

The Deming/Shewhart PDCA cycle is a model for learning and improvement that underlies the majority, if not all, of the known continual improvement methodologies (Moen and Norman, 2009). The DMAIC roadmap that guides Six Sigma continual improvement projects, as well as the DFSS roadmaps, are examples of that fact (Klefsjö *et al.*, 2006; Jones *et al.*, 2010).

Table IV describes and compares the core activities that are developed under the DMAIC framework (Montgomery and Woodall, 2008) and the main objectives of the PDCA cycle for learning and improvement (Moen and Norman, 2009). Table V, by its turn, compares the activities of the IDOV roadmap (Antony, 2002), usually used in DFSS projects, with the PDCA cycle.

For this topic, the following integration guidelines can be formulated:

- *Guideline 22*. The successful planning, execution, and completion of a Six Sigma project, either using the DMAIC or the DFSS approach, contributes to the continual improvement of the effectiveness and/or efficiency of the organisation's QMS based on the ISO 9001 standard.
  Applicable ISO 9001 clauses: 4.1f), 8.1, 8.5.1.
- *Guideline 23*. The DMAIC roadmap can be adopted as the continual improvement process of an organisation, even if it needs to be tailored to its specific needs.
  Applicable ISO 9001 clauses: 8.1, 8.5.1.

	Internal data sources	External data sources
Retroactive data sources	Processes efficiency key performance indicators (e.g. average setup time for machines, percentage of waste material) Human resources key performance indicators (e.g. employee satisfaction, utilization level of the personnel) Product conformity key performance indicators (e.g. process capability, rate of defective products) Financial key performance indicators (e.g. percentage of invoices with errors, production costs compared to the sales volume) Available data and information generated internally (e.g. existing engineering reports, reports of already performed internal audits)	Customer complaints Existing customer surveys Customer-related key performance indicators (e.g. customer satisfaction index, customer retention) Suppliers-related key performance indicators (e.g. percentage of deliveries on time, percentage of defect-free lots received) Partners-related key performance indicators (e.g. duration of partnership, number of joint ventures with partners and value added) Available data and information generated externally (e.g. existing market research studies)
Proactive data sources	Brainstorming sessions to collect improvement and/or innovation ideas from the personnel Forecasting and life cycle analysis of the organisation's products, services, processes and technologies Internal audits	Benchmarking studies Customer surveys Perform SWOT analysis Brainstorming sessions with suppliers to collect ideas, suggestions, gather their needs, wants and expectations Brainstorming sessions with business partners to collect ideas, suggestions, gather their needs, wants and expectations Second or third-party audits

Table IV.
Classification matrix of data sources

- *Guideline 24.* The IDOV roadmap for product and process design, or another DFSS roadmap, can be adopted as the design and development process of an organisation, even if it needs to be tailored to its specific needs.
  Applicable ISO 9001 clauses: 7.1, 7.3.
- *Guideline 25.* The improvement actions developed during the "improve" phase of the DMAIC roadmap are similar to the concept of corrective actions described in the ISO 9001:2008 standard.
  Applicable ISO 9001 clauses: 8.5.2.

Guidelines for "management review"

Management review (clause 5.6 of ISO 9001) is a formal and regular process where top management of an organisation reviews the QMS for its effectiveness in enabling the organisation to meet requirements of customers and other interested parties (Hoyle, 2003). Regular management reviews ensure that the QMS is still suitable, adequate, and effective in an ever-changing organisational, market, and external factors conditions.

In addition, management review should be prepared beforehand in order to be effective. This allows top management to assess the effectiveness of the QMS based on the quality policy and the quality objectives, and to define opportunities for

DMAIC phases description (Montgomery and Woodall, 2008)	DMAIC	PDCA	PDCA phases description (Moen and Norman, 2009)
Identify and/or validate the business improvement opportunity Define critical customer requirements Document (map) process Establish project charter	*D*efine	*P*lan	Plan a change or test, aimed at improvement
Determine what to measure Manage measurement data collection Develop and validate measurement Determine sigma performance level	*M*easure		
Analyse data to understand reasons for variation and identify potential root causes Determine process capability, throughput, cycle time Formulate, investigate, and verify root cause hypothesis	*A*nalyse		
Generate and quantify potential solutions Evaluate and select final solution Verify and gain approval for final solution	*I*mprove	*D*o	Carry out the change or test, preferably on a small scale
Develop ongoing process management plans Mistake-proof process		*C*heck	Check/study the results. What did we learn? What are the results?
Monitor and control critical process characteristics Develop out of control action plan	*C*ontrol	*A*ct	Adopt the change or abandon it, or run through the cycle again

Table V.
DMAIC roadmap phases compared with the PDCA cycle

improvement and the need for changes based on the results of data analysis, and on the content of relevant business information.

Management reviews can play an important role within a Six Sigma program, as shown in Figure 4 and described in the following guidelines:

- *Guideline 26*. Top management reviews can be used to assess the effectiveness of the Six Sigma program and to develop improvement actions targeting identified areas for improvement of the Six Sigma program itself.

  Applicable ISO 9001 clauses: 5.6.

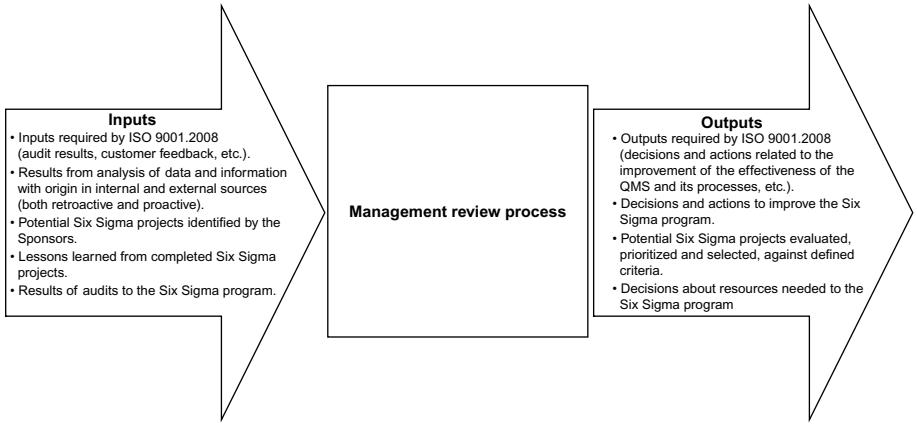


Figure 4.
ISO 9001:2008 management review process in the context of a Six Sigma program

- *Guideline 27.* Potential Six Sigma projects, previously identified when analysing data and information with origin in both internal and external sources, should be evaluated, prioritized and selected by the organisation's top management. In this sense, the Six Sigma project selection process can be performed during the management review regular meetings.

  Applicable ISO 9001 clauses: 5.6.

4. Conclusions

The effective integration of a Six Sigma program with existing management systems, particularly with QMS, has been well recognised as a crucial factor to the successful deployment of Six Sigma in an organisation. In addition, many agree that there are mutual benefits in combining and articulating Six Sigma with the requirements of the ISO 9001 standard.

Despite the fact that many authors consider that one of the Six Sigma emerging research trends is its integration with QMS based on ISO 9001, from the literature review we can conclude that the majority of the discussion on this subject has remained to a generic level, limited to a small portion of the potential integration modes, focused on the Six Sigma DMAIC methodological approach, and did not indicate how the ISO 9001 clauses can be linked to a Six Sigma program.

The following relevant topics were carefully addressed in this paper:

- The available literature on the subject was compiled, and the information contained therein was exhaustively analysed, explored, compared and organised into main groups of ideas.
- The literature review led to the identification of the main similarities and differences between Six Sigma and ISO 9001 QMS, enabling us to determine a set of linkages that facilitate the integration of both approaches.
- An integration framework, containing a total of 27 comprehensive guidelines, distributed over a set of 8 types of synergies, to systematically articulate a Six Sigma program with a ISO 9001 QMS, was proposed.
- All the integration guidelines were linked to the ISO 9001 related clauses and subclauses.

The main contributions and advantages arising from the integration guidelines proposed in this paper are as follows:

- They cover a wide and complete spectrum of ISO 9001 requirements, and range almost every relevant aspect of Six Sigma as a system, methodology and metric.
- They provide objective and practical guidance to develop, implement, maintain and improve an ISO 9001 QMS that is capable and flexible enough to incorporate the principles and practices inherent to a Six Sigma program.
- On the contrary to the current integration models, the articulation of ISO 9001 with the Six Sigma as a methodology is not limited to the DMAIC roadmap, but also includes linkages with the DFSS approach.
- The linkages that were identified between the roles of a Six Sigma program and those inherent to an ISO 9001 QMS allow organisations to take full advantage of

available human resources, which are often scarce particularly in small and medium enterprises, when they decide to adopt both approaches.

- They provide comprehensive guidance in order to adopt Six Sigma projects as the engine to the continual improvement of the ISO 9001 QMS, since Six Sigma provides specific roadmaps based on the PDCA cycle, and tools/techniques to support data analysis and decision-making.
- Systematic procedures to identify potential Six Sigma projects, based on a set of activities that need to be performed to meet the ISO 9001:2008 requirements, were described. Data analysis, evaluation of gaps between quality objectives and results actually achieved, analysis of internal audits conclusions, measurements of customer satisfaction, are examples of such activities.
- A systematic approach of how the management review process of an ISO 9001 QMS can be used to evaluate and select potential Six Sigma projects, assess the main strengths and areas for improvement of the Six Sigma program and decide on actions to improve its effectiveness was presented and discussed.
- The effectiveness of the process management activities required by ISO 9001 can increase if Six Sigma DMAIC roadmap and some of its tools, such as SIPOC diagrams and system diagrams, are used as a support to those activities.
- They enable quality objectives defined for the QMS to be aligned with Six Sigma project goals.
- Each integration guideline was carefully linked to the clauses of the ISO 9001 standard, so that it can be easily scoped and adapted to the specific context of an organisation.

Regardless the mentioned advantages, there are also potential limitations of integrating Six Sigma with a QMS based on the ISO 9001 standard that are outlined below:

- ISO 9001 QMS are often criticised for excessive procedural formalisms, thus adding additional constraints to an effective deployment of Six Sigma projects. Since the standard's version of 2000 was published, QMS became much simpler and useful for companies; however efforts still need to be made in order to minimise the use of unnecessary documentation and records, while keeping QMS processes and procedures simple.
- Six Sigma is, many times, associated to a continual improvement initiative that requires the employment of many complex statistical tools, so people involved in the ISO 9001 QMS may tend to be sceptic, not only about their role within the Six Sigma program, but also about the practical usefulness of the program to the organisation. To help to overcome this potential problem, Six Sigma should be recognised as a management system that encompasses all the levels of the organisation.
- Six Sigma and ISO 9001 QMS can be perceived as two distinct initiatives, and the linkages between them may not be well-understood by the personnel. By capturing the relationships between Six Sigma and the ISO 9001 clauses and subclauses, this potential limitation can be overcome.

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