

## Relationship between Quality Planning and Innovation

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**Abstract:** *This paper aims to improve the strategic quality planning in accordance to ISO 9001 requirements. The study's specific objectives are: examining ISO 9001 requirements on quality strategic planning; clarifying relationship between quality planning and innovation planning, in the context of the Innovation Management System implementation. The methodology of the study consists on a systematic review of the requirements of ISO 9001 standard on quality planning and case study approach of the connection between quality planning and innovation projects. All those represent a starting point for further analysis aiming the establishment of a performant quality-innovation integrated management system that may lead companies to high competitiveness.*

**Key-words:** *strategic quality planning, ISO 9001, quality and innovation relationship, CEN/ TS 16555-1 - Innovation Management System*

### 1. Introduction

The quality orientation is undoubtedly one of the core elements of management theory and practice over half a century. The literature gives wide spaces to the evolution of the quality concept and quality approach, which culminated in the emergence of the international standards for quality systems, namely ISO 9000 family of standards. According to ISO 9000 (CEN/ TS 16555-1, 2013), Quality Management System (QMS) is “a set of interrelated or interacting elements that organizations use to formulate quality policies and quality objectives and to establish the processes that are needed to ensure that policies are followed and objectives are achieved”. Quality term is also defined as “the degree to which a set of inherent characteristics fulfils a set of requirements”.

The ISO 9000 family for quality management systems are the first standards for management systems, and they have a worldwide recognition. According to data released by the ISO Survey of Management System Standard Certifications, a

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number of 1.138.155 QMS - ISO 9001 certificates have been issued in 2014 (ISO Survey, 2016).

The efficacy of the QMS implementation represents the subject of a large number of studies (Kaziliūnas, 2010; Kumar and Balakrishnan, 2011; Lee et al., 2009; Lo et al., 2009), the benefits being expressed by: improving product performance, reducing losses, increasing customer satisfaction and efficiency. The publications signal also some difficulties and weaknesses in the implementation of quality management. Thus, the survey of statistical data over a period of 10 years, in pharmaceutical domain, indicates that most companies still have significant gaps in their quality system (Allanson, 2015). There were identified 10 major causes, including: inappropriate measures used to indicate how well the quality system is working, no regular management review of the quality system, no formal system to drive the continuous improvement of quality, existence of a compliance culture rather than a quality culture. In our opinion, one of the main causes that make the quality approach inefficient is a deficient quality planning, without considering strategic changes that the organization must do in order to maintain or improve its competitive position (Popescu, 2013).

This paper is focused on strategic approach on quality, which involves harmonizing quality objectives with organizational strategy and implementation of changing projects/ innovations to achieve a sustainable success. The study examines distinctly: the requirements of ISO 9001 on strategic quality planning; the relationship between quality planning and innovation planning, in the context of the Innovation Management System implementation.

The methodology of the study consists on a systematic review of the requirements of ISO 9000 standards on quality planning. The research includes also a case study approach of the connection between quality planning and innovation projects. The literature is extensively reviewed in order to achieve the paper objectives.

## **2. ISO 9000 and strategic approach on quality, relation with innovation**

Overall, the purpose of the ISO 9001 (ISO 9001, 2008; ISO 9001, 2015) is to facilitate the trade between organizations. The application of this standard ensures that the organization can repeatedly achieve and deliver products with certain features. Consequently, ISO 9001 focuses only on the processes that directly affect product quality. ISO 9001 processes refer to planning the product and service quality, establishing work rules to prevent nonconformities, controlling quality of product and processes, and reducing identified non-compliances by corrective actions. Repeated application of this activities cycle defines continuous

improvement mechanism, known as the PDCA cycle (abbreviation for Plan-Do-Check-Act).

In the sense that is given in quality management, continuous improvement refers to small, incremental changes, which decrease losses through systematic actions of people involved in process. The continual improvement is one cornerstone of QMS. The extent and effectiveness of the improvements is an important criterion for characterizing QMS performance. But these improvements are not enough to ensure sustainable development of an organization. In addition to the improvement based on corrective actions it is necessary to bring the organization to new levels of performance through major changes, based on innovation. The achievement of these changes is in connection with quality planning and requires a strategic approach of quality and innovation (Marquardt, 1999; Popescu, 2013).

The strategy is the management instrument which sets out a vision for the organization future. Strategic planning ensures consistency of the important decisions and organization performances. This underpins planning activities for shorter periods, including planning projects for change necessary to implement the strategy and to achieve quality objectives.

Most quality planning problems are due to lack of coherent strategies that ensure competitive advantage and improve economic performance of the organization (Popescu, 2013, 76-86). One example is presented below.

S.C. IGRAM S.R.L. is a small Romanian firm, with 12 employees, having trailers manufacture and sale as main activities. The outlet of this company is small and thus, the turnover and economic results are very low. This situation is caused both by the small size of the business and the low level of company technology. In order to improve its market position and business performance, the company has implemented an ISO 9001 quality management system. The quality policy established by top management reflects customer orientation and willingness to improve customer satisfaction by correctly defining customer requirements and reducing nonconformities. The company has established also the main quality objectives at the organization level and functions/ departments/ relevant processes. Those include:

- delivering products and services under specified conditions, in order to increase the customer satisfaction;
- preventing non-compliances in all phases of product manufacturing, decreasing them by 10%;
- training and motivating staff, material and moral stimulation of employees for continuous quality improvement;
- certification of the QMS conformity with the requirements of SR EN ISO 9001 standard.

The definition and control of the company processes, in accordance to ISO 9001 clauses, have provided the tools to avoid wastage of resources and reduce costs. But these actions did not have significant effects on the organization competitive position and economic results: the number of customers has remained small, a significant part of the market being occupied by selling trailers manufactured in foreign companies, both new trailers and in „second hand” system.

This situation is explained by the lack of a strategy for improving competitiveness appropriate to the specific business of the company. The ISO 9001 standard requires aligning quality policy and objectives with the organization's strategy, but companies often do not refer to the organizational context and the need to make strategic changes to improve their competitive position.

To help eliminate this deficiency, in the 2015 edition of ISO 9001 a new requirement was introduced, asking the organization to examine key success factors, internal and external (Clause 4.1 "Understanding the organization and its context"). This new clause refers to these factors as the context of the organization. This is fundamentally environmental scanning intended to answer the question: Who are we and how does our competitive environment looks like? This clause is followed by 4.2 "Understanding the needs and expectations of interested parties", which asks the organization to identify interested parties. The clauses 4.1 and 4.2 constitute the basis for quality planning which includes actions related to risks and opportunities, quality objectives and planning of changes.

The next example (see table 1) illustrates the link between strategy, quality objectives and change projects. If the organization defines as key objective at the business level increasing profit margins on certain products, then the quality objectives are:

- reduction of nonconformities costs - which causes direct economic advantages;
- improving consumer satisfaction - that might justify increasing the sale price.

Both situations are presented in table 1, which indicates in the last column the change actions necessary to achieve the objectives set.

Strategic Objectives	Quality Objectives	Ways to Improve
Increasing commercial profitability with 50%.	Reducing rate of internal nonconformities with 50% in the next 3 years. Improving customer satisfaction with 25% in the next 3 years.	Implementing Six Sigma Method. Reorganization of the service process.

Table 1. *Correlation between the overall strategic objectives and quality objectives*

The requirements related to strategy and innovation projects are better defined in ISO 9004 – “Managing for the sustained success of an organization - a quality management approach”. Many studies associate this standard with Total Quality Management (Marquardt, 1999; Popescu et al., 2011) - the term commonly used for a more complex approach to QMS, defining "a systematic driving performance of the organization, involving new strategies of management, changes in culture and infrastructure, tools and techniques to persuade everyone in the organization to collaborate and enable continuous improvement of quality defined by the client" (Koller, 1995). In ISO 9004 standard, strategy and innovation appear as distinct processes.

Recognition of innovation importance is highlighted by the innovation introduction among the ways to improve quality, in the 2015 edition of ISO 9001. The extension of the improvement processes from incremental (continuous) improvements to a broader approach that includes the improvement as a result of periodic breakthroughs, innovation based changes and reorganization, explains the new title, "Improvement" (clause 10, ISO 9001: 2015.), instead of "Continual improvement" (clause 8.5.1, ISO 9001: 2008).

All these changes are designed to lead to the correct approach of the quality planning based on the organization's strategy, and emphasize that innovation is more than a component/ process of QMS. These changes are based on understanding the increased role of innovation in organization and the importance of innovation as a driver of efficiency and sustainability. Successful organizations have developed management systems that realize innovation through systematic planning and control processes. Given this situation, we show below the elements of Innovation Management System (IMS) and connections with QMS, with focus on quality and innovation planning.

### **3. IMS & QMS relationship, integrated planning of innovation and quality**

In a broad sense, innovation defines the introduction of something new in order to obtain useful results. According to the OECD classification (OSLO Manual, 2005), innovation refers to “the implementation of a new or significantly improved product (good or service) or process, a new marketing method or a new organizational method in business practice, workplace organization or external relations.”

Most prior works address quality-innovation relationship in terms of TQM (Popescu et al., 2011; Prajogo and Sohal, 2001). Some studies say that quality management creates a fertile environment for innovation, QMS being considered as a driver for innovation (Castilo et al., 2008; Prajogo and Sohal, 2003).

The increased importance of innovation has led to development of models for achieving a high level of innovation within organization (OSLO Manual, 2005),

which culminated with the standards for Innovation Management Systems. We can mention: the Romanian standard SR 13547 (2012) -"Business development through innovation" and the European standard CEN/ TS 16555-1 (2013) -"Innovation Management - Innovation Management System" (IMS), which present the principles and guidelines for a systematic approach to innovation within organizations. The scheme below (see figure 1) shows the IMS model (CEN / TS 16555-1, 2013).

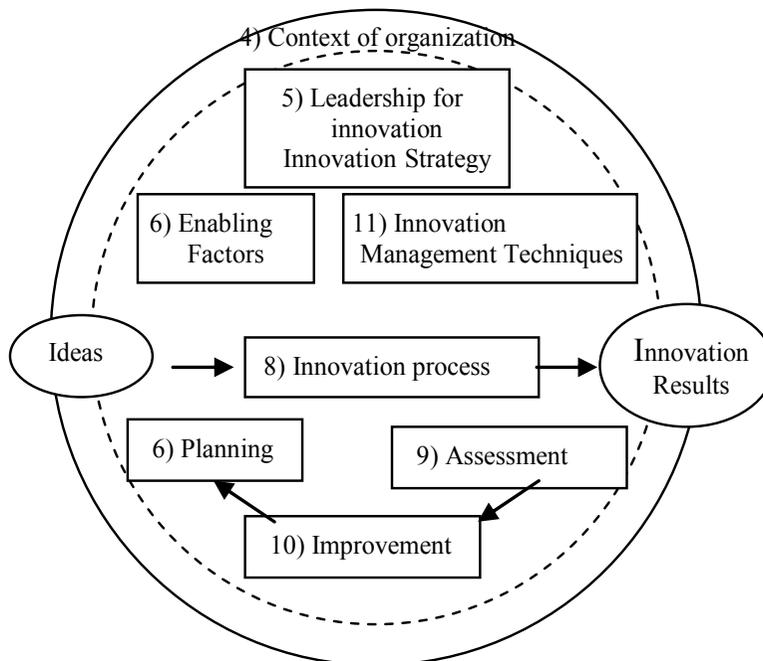


Fig. 1. *IMS Model - CEN/ TS 16555-1 (2013)*

One can see that the system has a similar configuration with the model ISO 9001 (2015) - QMS - based on processes approach. IMS scheme illustrates also the cyclical engagement of planning, execution, control and improvement activities (PDCA mechanism). Finally, one can see the inclusion of leadership as IMS macro process: the requirements of this chapter underline the decisive role of senior management in achieving innovation. Its responsibility includes: setting direction (strategies and policies), establishing employees' responsibilities, communication, and developing an organizational culture open to innovation.

Another important element, not visible in the figure, refers to the focus on human resource and problem solving in the formal and informal ways, in regards

with: introducing norms of organization that promote staff participation in change processes, using methods of stimulating creativity, promoting leadership and other specific values to achieve excellence etc. According to specialists, primary innovation is about people (Popescu et al., 2011).

Even summary, the above description highlights the similarities between IMS - CEN / TS 16555-1 (2013) and QMS - ISO 9001 (2015). The similitude of the two models is not accidental: the standardization bodies work to harmonize the standards for management systems in order to facilitate their implementation by organizations. Integration of QMS and IMS is already a subject of study (Maier et al., 2016).

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In our opinion the integration of the two systems is not only beneficial, but mandatory, ensuring harmonization of actions in relation to the overall interests of the organization and optimizing the use of resources.

Management Systems integration aims, among other things, at better alignment of the specific goals of the two areas. The figure 2 shows the connections between the quality and innovation systems on the strategic planning process. We can see that both quality and innovation objectives are subordinated to the general strategic objectives of the organization.

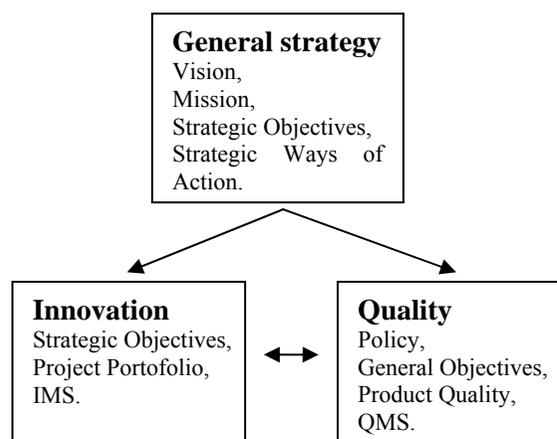


Fig. 2. *Connections between innovation and quality planning*

It should be emphasized that strategic changes is not only about improving quality, but also environmental performance, business expansion into new markets, modification or relocation of production capacities etc. The next illustrative example refers to GlaxoSmithKline (GSK) - a multinational company which is in the top 25 in the worldwide drugs production and distribution.

The maintenance of company's leading position is due to its modern management system, in which the products quality and processes is a central axis. Realizing great rhythms of products renewal through research and development conducted by GSK is also a key success factor.

In 2013, the company announced its decision to restructure the drugs manufacture, consisting in the liquidation of one of its factories from Romania. The main reason for reducing the production capacity of the company is the expiration of the protection period for a large number of original drugs (products protected by patents), with negative consequences on revenue. There was an estimated loss of about 50 Billions \$, caused by the fact that after the expiration of original drugs protection, generic drugs appear on the market with prices up to 85% lower. Given this perspective, the company decided to restructure the business, namely reducing production capacity to manufacture generic products and strengthening research and development of new products.

It is noteworthy that GSK is one of the companies that have implemented quality management principles and systematically applies continuous improvement. So, there were not the low quality of the products and manufacturing technologies the factors which determined this strategic decision. The expected changes are in line with company strategy that focuses on three strategic priorities to ensure economic growth, reduce risk and improve long-term financial performance. These priorities are: developing a diversified global business, deliver more high-value products, and simplification of the operating model. (<http://www.gsk.com>)

The above example is not unique; the success of top companies is based on the continuous effort of transforming the business mix towards higher value to market opportunities and more profitable technologies. Not only large companies but also SMEs are increasingly faced with the issue of innovation in the current context characterized by fierce competition, computerization and globalization. Nowadays innovation is a “sine qua non” of existence for any organization (Popescu, 2016, pp.37). In accordance to this idea, Peters says: “Continuous improvements occurring in the running for improvement are admirable ... just to a point. ... The only sustainable competitive advantage comes from overcoming competition through innovation.” (Peters, 2010, p. 55).

#### 4. Conclusions

The main result of the study consists of the analysis of quality planning process, considering the ISO 9001 requirements. The study highlights the connections between quality planning and strategy, respectively change/ innovation projects on which strategy implementation and achieving quality objectives depend. A novelty is emphasizing the idea that innovation is not only an element of QMS, but a key factor of organization success, whose modern approach supposes the implementation of IMS, similar to quality systems. Integration of the two systems creates prerequisites for the optimization of the planning quality and innovation, both based on the organization's strategy as a starting point.

This paperwork is important for managers and specialists in quality and innovation, supporting the adequate application of requirements for quality planning, in accordance with the reference standard. At the same time, it represents a starting point for the development of future studies on the connection of quality and innovation approach, for the achievement of an Integrated Management System – Quality and Innovation.

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