

Risk and ISO 9001: A Systematic Literature Review



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Abstract The search for excellence, related to the processes, products and services quality and to the market requirement, makes organizations to implement their Quality Management Systems (QMS). In this context, with ISO 9001 standard revision, published in 2015, a new requirement is established: risk-based thinking. The main focus of this article is to provide information, by doing a Systematic Literature Review (SLR), about the state of the art of Risk and ISO 9001 standard, identifying the risks' approaches used by the organizations and finding gaps and inconsistencies in the literature. This SLR was conducted as follows: (a) establishing the research main question; (b) locating studies (defining the research sources, timing and criteria); (c) analysis and synthesis (supported by QSR NVivo); and (d) findings and conclusions. The main field of research was chosen to answer the question "what kind of methodologies and methods, companies that have a QMS based on ISO 9001 can use as a support to the risk-based thinking requirement?" The paper's aim is also to contribute with companies who are looking forward to implement the Risk Management in their processes.

Keywords Risk · ISO 9001 · Quality management system

1 Introduction

Organizations have been facing a strong and competitive market besides high customer expectations, what makes them to look for ways to stay competitive. To reach that, companies try to improve the activities that add value to the process and business [1].

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J. Reis et al. (eds.), *Industrial Engineering and Operations Management I*, Springer Proceedings in Mathematics & Statistics 280, https://doi.org/10.1007/978-3-030-14969-7_22

The search for excellence is intimately related to their products, services and processes' quality and to achieve it, many organizations opt for a Quality Management System (QMS) implementation, supported by several models and tools [2]. Besides not being considered a TQM model, the ISO 9001 standard can be a good start for companies that are at the beginning of the quality achievement process [3].

The ISO 9001 standard, elaborated by the Technical Commit of the International Standardization Organization (ISO/TC 176), defines requirements to support organizations on the quality and conformity of their products and services, fulfilling customers' necessities [4]. International Organization for Standardization (ISO), in 2016, announced that there are 1,643,529 valid ISO 9001 certificates worldwide, being only 7% in ISO 9001: 2015. In Brazil, there are 20,908 certified companies, 3% in ISO 9001:2015 [5].

On its latest version, ISO 9001:2015 contains changes apparently easy but that implies big challenges for the organizations [6, 7]. One of the most significant changes was the risks approach, implicit on the preview versions of the standard and now treated as "risk-based thinking", as a requirement for the entire organizational environment. This concept seeks to instigate organizations to be more careful and to think in long-term [3, 8–10].

The risk management is a very comprehensive term and the researches related to it are in contrast, much specifics, which always leads to a gap, even small, to be filled [11]. This can be inferred from a number of studies that have analyzed risk management in the context of companies QMS and ISO 9001 implementation processes.

It is important to observe that being in the Digital Transformation Era, organizations have to adapt their strategies and models for business processes to the digital reality [12], what can also be related to the risk-based thinking approach, in terms of long-term thinking and opportunities to company's growth.

In order to assist further research in this field, the paper aims at finding relevant literature contributions on risks, with particular interest on its relation with ISO 9001 standard, in the aspects of its emerging issues, most frequent talked themes and existing gaps. This paper was structured as follows: the first section covers the introduction; Sect. 2 characterizes this paper's research methodology; and Sect. 3 describes the findings and conclusion.

2 Research Methodology

To conduct the study, the authors based on a systematic literature review (SLR) which is a methodology used by academic researchers to manage knowledge diversity, mapping and evaluating the existing intellectual territory, being capable to develop and increase the subject aspects, contributing to the state of the art [13].

The SLR was conducted as follows: (a) establishing the research main question; (b) locating of studies, where it is established the search sources, timing and criteria; (c) analysis and synthesis (supported by QSR NVivo); and (d) findings and conclusions

SLR Phases	Objective	Method	Tool
(1) Research question establishment	<ul style="list-style-type: none"> Establishing the question (main field) that will guide the research 		
(2) Locating Studies	<ul style="list-style-type: none"> Locating, selecting and evaluating relevant literature 	<ul style="list-style-type: none"> Definition and use of Electronic Databases 	<ul style="list-style-type: none"> Scopus (Elsevier) and Web of Science (ISI)
(3) Study, Selection and Evaluations		<ul style="list-style-type: none"> Definition of search period 	<ul style="list-style-type: none"> 2008 – 2018
		<ul style="list-style-type: none"> Definition and use of inclusion/exclusion criteria 	<ul style="list-style-type: none"> Inclusion: Risk terms related to organizational processes, management, Quality Management System and ISO 9001 – Peer reviewed articles published in Journals or Proceedings of International Conferences Exclusion: Risk terms related to the words “project”, “health” and “software” – relevance of the papers (citation) – title/abstract analysis (adequation)
	<ul style="list-style-type: none"> Definition and use of search strings 	<ul style="list-style-type: none"> Risk Management, ISO 9001 	
		<ul style="list-style-type: none"> Selection of method for synthesis and analysis of qualitative research 	<ul style="list-style-type: none"> Thematic Synthesis
(4) Analysis and Synthesis	<ul style="list-style-type: none"> Synthesizing and analysing selected articles 	<ul style="list-style-type: none"> Coding and extraction of data 	<ul style="list-style-type: none"> QSR NVivo
(5) Reporting and Using the Results	<ul style="list-style-type: none"> Reporting of findings 		

Fig. 1 SLR phases, methods, criteria and tools (Source adapted from [14])

[14, 15]. The topics (a) and (b), described previously, are discussed on this section as follows.

2.1 Locating of Studies

The SLR process (Fig. 1) was conducted as follows: the main field of research was choose to answer the question “what kind of methodologies and methods, companies that have a QMS based on ISO 9001 can use as a support to the risk-based thinking requirement?”. The location of articles considered the key words in two electronic databases: Scopus and ISI Web of Science (WoS), citation indexes that coverage mainly focuses on journals [16]. Li et al. [17] affirms that WoS “is the oldest citation database with both bibliographic data and citation data going back to 1900”. Besides being oldest and having the longest coverage, WoS does not index all of the journals that are found in Scopus, what aims to the fact that Scopus “has a larger proportion of exclusive journals and this is the case in all fields” [16].

The period of research was established based on the ISO 9001 standard transition process: its past edition was published in 2008 and replaced in 2015. In terms of key words, it was observed macro themes, which are “risk” and “ISO 9001”. The standard

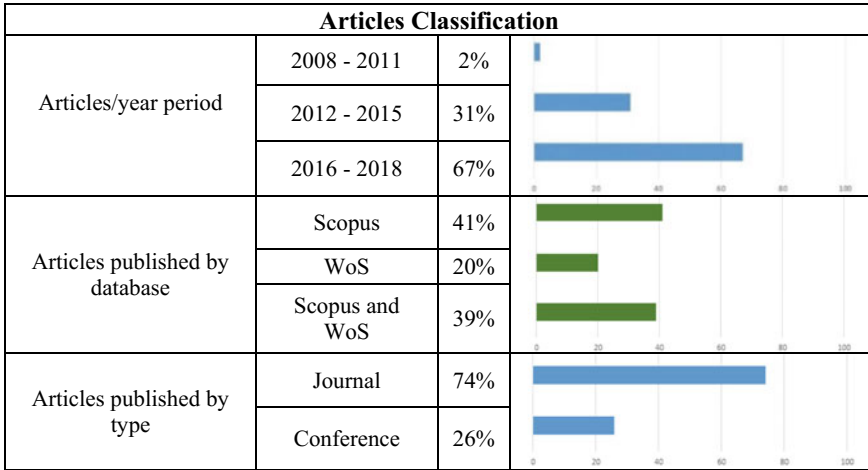


Fig. 3 Articles classification (elaborated by the authors)

In parallel with the investigation above, the articles were analyzed by year of publication, indexed databases and types of publications (see Fig. 3); Table 2 presents the selected articles list.

The main analysis of the present article is described in this section. To answer the question proposed at the beginning of the SLR, the 46 papers were analyzed by methodologies, methods, models and/or tools presented in (see Fig. 4).

It was found from the selected papers, 16 (P1; P3; P4; P6; P8; P11; P12; P13; P14; P19; P23; P28; P31; P32; P39; P44) that do not mention any of the topics listed above. Therefore, besides presenting subjects related to risks, quality management system and ISO 9000, they were not used to compose the final chart. All of the others, propose, explain or mention some methodology, method, model or tool to support the risk management activities and to the “risk-based thinking” required by ISO 9001.

It can be inferred from the Fig. 4 that 15 papers describe methodologies, while 22 present some method/model/tool. The most frequent methodologies observed were ISO 31000 and PDCA cycle. Regarding to them it is important to highlight that ISO 31000 is based on PDCA, prescribing a risks approach unfolded in: to identify, to analyze and to evaluate (P—plan), to treat (D—do), to monitor (C—check) and to analyze (A—act). The most related tool was the FMEA (Failure Modes and Effects Analysis), probably due to its wide dissemination and customers’ requirements (for example automotive and aeronautic sectors and healthcare products). However, FMEA has its limitations.

The analysis process can become cumbersome and long, with possible costs for application; and the method is not prepared to discover complex failure modes involving various failures or subsystems. To solve that question it should be used the FTA (Fault Tree Analysis) [18].

Table 2 Articles included in the literature review by author(s)/year, title and database

No.	Author(s)/year	Title	Database
[P1]	Anttila & Jussila, 2017	ISO 9001:2015—a questionable reform What should the implementing organizations understand and do?	WoS
[P2]	Atan, Ramly, Musli Mohammad, 2017 [21]	A review of operational risk management decision support tool	Scopus
[P3]	Barata, Rupino and Costa, 2013 [22]	Developing an IS quality culture with ISO 9001: Hopefully, a never ending story	Scopus
[P4]	Boiral, 2011 [23]	Managing with ISO Systems: Lessons from Practice	WoS/Scopus
[P5]	Budaj and Hrnčiar, 2015 [24]	The Importance of Risk-Based Thinking for Enterprise Performance Planning	WoS
[P6]	Chen and Chang, 2017 [25]	A practical flow regarding 2nd party audit on quality proficiency in supplier management	Scopus
[P7]	Chiarini, 2017	Risk-based thinking according to ISO 9001:2015 standard and the risk sources European manufacturing SMEs intend to manage	Scopus
[P8]	Da Fonseca, 2015 [26]	ISO 14001:2015: An Improved Tool for Sustainability	WoS/Scopus
[P9]	Emetumah, 2017 [27]	Integrated management systems as a risk management tool: Combining ISO 9001, ISO 14001 & OHSAS 18001 standards in process industries	WoS/Scopus
[P10]	Ezrahovich et al. 2017 [28]	Risk-based thinking of ISO 9001:2015—The new methods, approaches and tools of risk management	Scopus
[P11]	Fonseca and Domingues, 2017	How to succeed in the digital age? Monitor the organizational context, identify risks and opportunities, and manage change effectively	Scopus
[P12]	Fonseca, 2015a	FROM quality gurus and TQM to ISO 9001:2015: A review of several quality paths	WoS/Scopus
[P13]	Fonseca, 2015b	ISO 9001 Quality Management System through the lens of Organizational Culture	Scopus
[P14]	Galetto, Franceschini and Mastrogiacomio, 2017 [29]	ISO 9001 certification and corporate performance of Italian companies	WoS/Scopus
[P15]	Giannetti and Ransinf, 2016 [30]	Risk based uncertainty quantification to improve robustness of manufacturing operations	Scopus

(continued)

Table 2 (continued)

No.	Author(s)/year	Title	Database
[P16]	Golaś, 2014 [31]	Risk Management as Part of the Quality Management System According to ISO 9001	Scopus
[P17]	Golaś, Mazur and Gruszka, 2016 [32]	Improving an organization functioning in risk conditions in accordance with ISO 9001: 2015	WoS
[P18]	Gorlenko, 2015	Development of Management Methodology for Engineering Production Quality	WoS/Scopus
[P19]	Harafonova, Zhosan and Yankovo, 2017 [33]	Distinctions and features of ISO 9001:2015 standard implementation in the context of social and strategic development of enterprises	WoS
[P20]	Harasymiuk and Barski, 2016 [34]	Risk management as a determinant of the effectiveness of the quality management system in a building company	WoS
[P21]	Kline and Hutchin, 2017 [35]	Enterprise risk management: A global focus on standardization	Scopus
[P22]	Kotek et al. 2016 [36]	Risks in industrial management systems	Scopus
[P23]	Lenning and Gremyr, 2017 [37]	Making internal audits business-relevant	Scopus
[P24]	Liu Qi et al., 2012 [39]	Modeling of Risk Treatment Measurement Model under Four Clusters Standards (ISO 9001, 14001, 27001, OHSAS 18001)	WoS/Scopus
[P25]	Liu, He and Cui, 2017 [38]	Product assembling quality risk analysis approach based on RQR chain	Scopus
[P26]	Luburić, 2015 [40]	Quality management principles and benefits of their implementation in central banks	Scopus
[P27]	Luburić, 2016 [41]	Knowledge and learning in terms of operational risk management in the financial and banking systems	Scopus
[P28]	Medić, Karlović and Cindrić, 2016 [42]	New standard ISO 9001:2015 and its effect on organizations	WoS
[P29]	Nováková, Pauliková and Cekanová, 2017 [43]	Risk Management as part of a Quality Management System in Woodworking companies	WoS/Scopus
[P30]	Pacaiová, Sinay and Nagyová, 2017 [44]	Development of GRAM—A risk measurement tool using risk based thinking principles	WoS
[P31]	Parra-Lopez et al. 2016 [45]	ISO 9001 implementation and associated manufacturing and marketing practices in the olive oil industry in southern Spain	WoS/Scopus

(continued)

Table 2 (continued)

No.	Author(s)/year	Title	Database
[P32]	Psomas, 2013 [46]	The effectiveness of the ISO 9001 quality management system in service companies	WoS/Scopus
[P33]	Rebelo, Silva and Santos, 2017 [47]	The integration of standardized management systems: managing business risk	WoS/Scopus
[P34]	Rewilak, 2015 [48]	MSA Planning—A proposition of a method	Scopus
[P35]	Rodriguez, 2017 [49]	Partial implementation of the Quality Management System by ISO 9001:2015. Case study	WoS
[P36]	Ruamchat, Thawesaengskulthai and Pongpanich, 2017 [50]	Development of quality management system under ISO 9001:2015 and Joint Inspection Group (JIG) for aviation fueling service	Scopus
[P37]	Rybski, Jochem and Homma, 2017	Empirical study on status of preparation for ISO 9001:2015	WoS/Scopus
[P38]	Sari et al., 2017 [51]	From ISO 9001:2008 to ISO 9001:2015: Significant changes and their impacts to aspiring organizations	WoS/Scopus
[P39]	Sartor et al., 2016 [52]	The SA8000 social certification standard: Literature review and theory-based research agenda	WoS/Scopus
[P40]	Savino and Brun, 2017 [53]	A fuzzy-based multi-stage quality control under the ISO 9001: 2015 requirements	WoS/Scopus
[P41]	Sitnikov and Bocean, 2015 [54]	The role of risk management in ISO 9001:2015	WoS
[P42]	Sitnikov et al., 2017 [55]	Risk management model from the perspective of implementing ISO 9001:2015 standard within financial services companies	WoS/Scopus
[P43]	Sousa, Nunes and Lopes, 2015 [56]	Measuring and Managing Operational Risk in Industrial Processes	WoS/Scopus
[P44]	Vasile, 2017 [57]	A critical approach of thinking risk-based existing in the new issue of ISO 9001: 2015 standard	Scopus
[P45]	Vasile, 2012 [58]	The improvement of the manufacturing processes of electric servomotors by applying the new editions of the international standards on the quality and environment	Scopus
[P46]	Wong, 2017 [59]	Risk-based thinking for chemical testing	WoS/Scopus

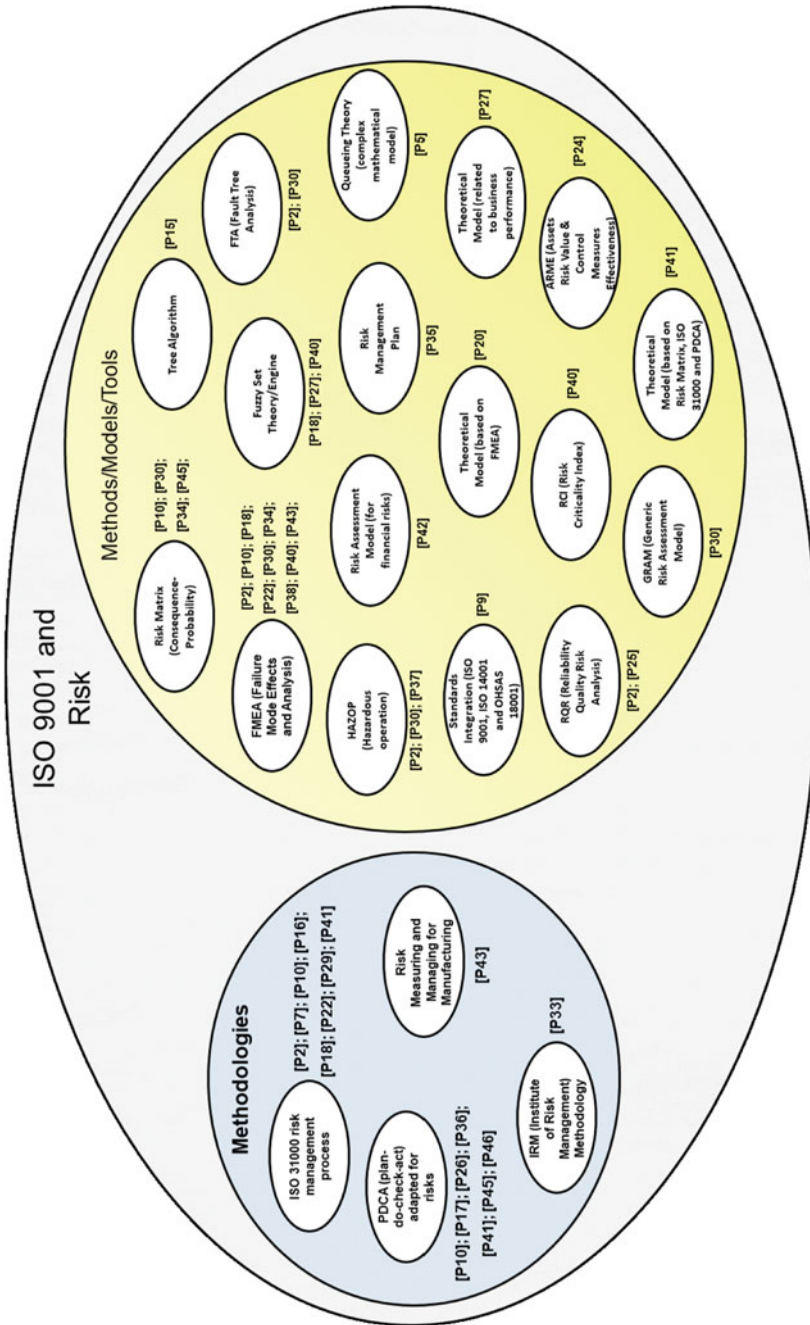


Fig. 4 Articles x methodologies/methods/models/tools

In addition, the mathematical formulation for the Risk Priority Number (RPN) is questionable and discussible since there is not any justification that, the product of Severity, Occurrence Probability and Detectability, results in the RPN [19, 20].

That tree factors are hard to be determined precisely because most of the FMEA's information is expressed by a linguistic form, what makes the interpretation in a subjective way for the reader [19]. The same problem can happen with the Risk Matrix.

3 Findings and Conclusion

Nowadays, researches in risks and ISO 9001 are increasing, once that the companies are in an embryonic and underdeveloped stage to integrate the risk management approach into their QMS's. This SLR addresses a current challenge for companies that want to maintain their QMS's, helping them to understand how the risks approach can be realized, supported by theoretical models designed and described, in the most part, in conformity to ISO 31000 methodology.

As it was described in the preview section, qualitative tools may have issues that, if not observed or treated adequately, can give unexpected results to the analysis. To avoid problems like that, companies should look for combinations of qualitative and quantitative tools that better adequate to their necessities.

However, it has much more to be done regarding to the applicability of the tools in the companies' contexts and about the efficiency of them. The authors suggest as future researches the application of some methodology in the context of certified companies, to evaluate its efficiency for the risk-based thinking approach.

Acknowledgements The authors thank CNPQ, CAPES, FAPEMIG, FUPAI and *Sisvoo Sistemas Eletrônicos Ltda.*, for funding support.

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