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Journal of Research and Reviews: A Journal of Drug Formulation, Development and Production ISSN: 2394-1944(Online)

Review, Volume 11, Issue 2, 2024

Submission Date: 12/04/2024

Acceptance Date: 04/06/2024

Published Date: 20/06/2024

Navigating Risk-Based Approaches in Quality Assurance: Strategies, Implementation, and Impact

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Abstract

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This review investigates the implementation of a risk-based approach within Quality Management Systems (QMS) as stipulated by ISO 9001:2015 regulations. It scrutinizes the challenges organizations encounter when transitioning to ISO 9001-2015 requirements, particularly focusing on the alignment of conceptual frameworks and processes among stakeholders. A key objective of this review is to propose a refined definition of "quality risk" and "risk-based thinking in QMS" to address the idiosyncratic characteristics of their application.

The transition to ISO 9001:2015 necessitates a fundamental shift in how organizations perceive and manage risks within their quality management frameworks. Central to this shift is the recognition that risk management is an integral part of achieving quality objectives and organizational success. However, achieving this integration poses significant challenges, including the need to redefine traditional notions of quality risk and risk-based thinking.

To address these challenges, organizations must adopt a proactive approach to risk management, wherein potential risks are identified, assessed, and mitigated throughout the entire product or service lifecycle. This necessitates the adoption of robust risk assessment methodologies that encompass both qualitative and quantitative approaches. By integrating these methodologies with the Software Development Life Cycle (SDLC), organizations can ensure that risk management becomes an inherent part of their development processes.

Furthermore, adaptability and flexibility are paramount in navigating the complexities of risk management within QMS. Organizational resistance to change, resource constraints, and cultural barriers often impede effective risk management practices. Overcoming these challenges requires a concerted effort to foster a risk-aware culture that encourages continuous improvement and innovation.

Looking to the future, this review identifies emerging trends in risk management within QMS, including the integration of artificial intelligence and machine learning algorithms for predictive risk analysis, and the heightened focus on cybersecurity risk management in an increasingly digitalized world. By embracing these trends and continually refining their risk management practices, organizations can enhance their resilience and competitiveness in today's dynamic business environment.

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Keywords:- Risk-based approach, Quality Management Systems, ISO 9001:2015, Risk assessment, Software Development Life Cycle (SDLC).

Introduction

The notion of a risk-based approach must be applied while creating an organization's Quality Management System (QMS) in accordance with ISO 9001:2015 regulations. It must also be ensured that actions are planned with reference to risks and varied opportunities. By avoiding discrepancies across all of the QMS's processes, this strategy aids in improving an organization's efficiency and service quality. The revised ISO 9000 standard reflects Hutchins' (2014) assertion that risk management is the way of the future for quality management.

The risk-based strategy used in firms' QMS is something they focus on especially. The reference literature (Abernathy, 2016; Akimov, 2004; Batova, 2015; Cagnin, Oliveira, and Cauchick Miguel, 2019;) and information gathered from quality service specialists indicate that organizations encounter difficulties when putting the risk-based approach into practice and passing internal and external audit procedures when transitioning to ISO 9001-2015 requirements. This is because stakeholders, including managers and staff members of businesses, as well as internal and external auditors, have inconsistent conceptual frameworks and processes.

Because of this, businesses frequently attempt—and occasionally even duplicate—to formalize the chosen methods for implementing the risk-based strategy in their QMS. The development and testing of methodological approaches regarding the selection of the risk-based approach in the QMS of organizations in various industries, based on their characteristics, is therefore our goal. We also aim to define and clarify certain terms in the field of risk management.

The characteristics of existing classifications include, but are not limited to, the degree of influence, object, topic (source), and reason for origin, the sphere of activity, and the organizational environment.

Nevertheless, none of these discuss the indication of risk classification based on how they are applied in management systems pertaining to the different facets of businesses; we believe that this ought to be published in scholarly journals. This is because of the growth of global

standardization in the management systems area, namely the adoption of a common methodology for the creation and modification of management system standards (also known as "high-level structure"). Based on this, new versions of the ISO 9001, ISO 14001, and ISO 45001 standards have been released. These versions include various risks, such as quality risk in the QMS, environmental risk in the environmental management system, and risk in the health, safety, security, and environment system (HSSE risk).

Even though the term "quality risk" appears in a number of publications, the scientific and normative literature does not provide a definition for the term that can be applied to the QMS of organizations. The term "risk" in the GOST R ISO9000-2015 standard refers to one of the general phrases and definitions for ISO standards on management systems; it is understood to mean the "influence of uncertainty" and is applicable to any management system used by businesses.

Nonetheless, the definition of "risk," which considers the unique characteristics of the QMS, specifically "risk in the field of quality," necessitates a specification akin to that of other management systems (GOST R ISO 14001-2016, ISO 45001:2018), in which the meaning of the pertinent term "risk" is normatively fixed (GOST R 57189-2016/ISO/TS 9002:2016, 2016; GOST R ISO 9001-2015, 2015).
The standard, which defines "risk" as "the impact of uncertainty on objectives," serves as our foundation for defining the phrase "quality risk." Risk is defined as “an event that impedes the achievement of objectives” by previous writers” It is important to note that the word “objective” is integral to this definition. The objectives specify the performance indicators, which are then used to identify potential events (risks) that could prevent the objectives from being achieved. The primary goal of a QMS is to satisfy customer needs (with regard to quality, cost, production schedule, availability of items, degree of after-sales support, etc.). A QMS's primary responsibility is to guarantee an organization's sustained growth so it may fulfill its quality-related objectives.

Regarding the aforementioned, we suggest defining "quality risk" as "the impact of uncertainty on the achievement of quality objectives aimed at ensuring the sustainable development of an organization through a balanced satisfaction of its stakeholders" and putting it into the scientific

literature. Its uniqueness resides in how it defines "risk" broadly and how it relates to an organization's quality management system (QMS), goals, and stakeholder interests. At the moment, not everyone agrees with the often-used term "risk-based approach." The bulk of scientific publications' definitions of this term do not account for the unique characteristics of its use in QMS. As a result, we suggest defining the phrase "risk-based thinking in QMS" more precisely. This is a "qualitative and/or quantitative assessment of the quality risks arising from the organizational environment, as well as decision-making to achieve the effectiveness of the organization's processes and QMS overall by maximizing the use of opportunities and preventing or reducing undesirable consequences." The unique aspect of our concept, which we call the "risk-based approach in QMS," is that it is restricted to an organization's QMS and the associated risks in the quality domain. It is highlighted that the organization's and its stakeholders' environments are its source and that they are an essential component of this environment, particularly during the risk identification stage. The goals for making decisions about the QMS and process management methodology are broadened. These include the avoidance or mitigation of unfavorable outcomes, making the most of newly available possibilities, and optimizing process and QMS performance overall.

Finding quality hazards is known as qualitative risk assessment; figuring out how serious they are—such as whether they are critical, major, or acceptable—is known as quantitative risk assessment.

The application of the risk-based approach by various methods, from the most basic to the formalized risk management methods (according to ISO 31000:2018 and GOST R ISO 311010-2010), has been provided to date by methodological studies by a variety of authors . Despite the fact that certain techniques and tools have been around for a long time in specific industries, like the food, medical, and automotive industries (HACCP) and the automotive industry (FMEA), the literature does not categorize these approaches according to their specificity or applicability (suitability) to different types of organizations. A variety of high-tech sectors and services, including banking, nuclear power, aerospace and telecommunications, healthcare, and healthcare, have implemented risk management techniques (ISO 31000) at the request of stakeholders .It follows that, in contrast to most other industries, including services and small

company organizations, the use of the risk-based approach in the QMS in these sectors is not problematic.

As a result, an organization must decide for itself what risk-based strategy to employ, and it might be difficult to defend this decision. In order to offer a solution, we proposed the hypothesis that any organization, regardless of size or industry profile, can implement a risk-based approach in a QMS; the complexity of the methods for doing so, however, primarily depends on the organization's environment, including the internal environment, as well as the maturity of its processes and QMS overall. Part I of this hypothesis is based on the ISO 9001-2015 standard, which states (item 6.1) that planning actions related to risks and possibilities must be done. It also states (item 1) that any organization, regardless of size, type, delivered production, or services rendered, is covered by the standard's scope of application. It should be underlined that, although ISO 31000:2018 can be applied to any business and its environment, introducing risk management is not required when implementing a new QMS model for an organization.

It does not, however, highlight its application in companies of any size, including small firms, in contrast to the ISO 9001-2015 standard. The ISO 31000:2018 standard states that the risk management process can have many application options tailored to the need to achieve an organization's goals as well as its external and internal environment. However, it can be challenging to implement its methodological approaches in small organizations. An organization can use the international standard ISO/IEC 31010-2009 to select the ways that are suitable for its purposes. The methods can be implemented based on the organization's environment. It has been established that a variety of factors pertaining to the legislative, technological, competitive, market, cultural, social, and economic environments at the international, national, regional, or local levels influence an organization's external environment. The maturity of the organization's existing management systems, such as the QMS and risk management systems, is what primarily defines the internal environment.

Thus, an organization's implementation of a sophisticated risk-based approach is linked to both the internal environment that facilitates this process and the external environment that supports it. The latter is the organization's developed QMS and the human component that goes along with it. As a result, the risk-based approach can be applied in a variety of ways and at varying

degrees of complexity. According to ISO 31000, the simplest method is A, which is based on defining quality objectives and planning changes in the QMS. The medium-complexity method is B, which uses elements of risk management. The high-complexity method is C. This is the conventional identification of the methods used in our research. However, there is difficulty in deciding which level of complexity for the risk-based approach methods in the QMS to be selected for a certain organization. In order to address this issue, methodological approaches for selecting the risk-based strategy in an organization's QMS must be developed, tested, and tailored to the unique characteristics of the business. [1]

Risk assessment methods

The next critical step is to assess the risks by taking into account their possible impact on the system and likelihood of occurrence once they have been identified. It is critical to evaluate each risk's degree of uncertainty and rank them according to importance. This can be accomplished in a number of ways, including by carrying out probability and impact analyses, keeping risk registries, and using risk matrices. After the risks have been located, classified, and ordered, they can be examined further to ascertain their probability and possible outcomes. [2]

There are various methods available to organizations for evaluating risks: asset-based, vulnerability-based, threat-based, qualitative, semi-quantitative, and quantitative. The risk posture of an organization can be assessed using any approach, but there are trade-offs with each one. There are various methods available to organizations for evaluating risks: asset-based, vulnerability-based, threat-based, qualitative, semi-quantitative, and quantitative. The risk posture of an organization can be assessed using any approach, but there are trade-offs with each one. [3]

Integration with SDLC

The duties carried out at each stage of the software development process are defined by the Software Development Life Cycle (SDLC), a conceptual model. This model provides you with a brief overview of the software life cycle during the development stage. In this specific article, we will talk about risk management at every stage of the SDLC model.

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Steps in SDLC Model

Although there are many different models for the Software Development Life Cycle (SDLC), the following steps are typically included in the SDLC:

1.Initial Analysis
2. System Evaluation and Determination of Requirements
3.System Development and Design
4.Testing of systems and integration
5.Testing for acceptability, operation, and installation
6.Upkeep
7. Removal [4]

The function of quality assurance in the software development lifecycle (SDLC) is not isolated; rather, it is a set of interconnected tasks that cover every stage of the SDLC. These activities encompass:

Requirement analysis: QA teams work together to define requirements right from the start of the project. It is their responsibility to guarantee that these specifications are clear, unambiguous, and compliant with testing.

Design Review: By verifying that designs adhere to set requirements and design standards, quality assurance extends its influence to expedite the designing process.

Test Planning: QA teams create thorough testing plans that include the testing methodology, resource requirements, project schedules, and the testing scope.

Code Review: To promote code quality, QA specialists conduct code reviews to evaluate compliance with best practices and coding standards.

Testing: QA personnel carry out carefully designed test cases and promptly submit any bugs found for fixing. They supervise the retesting process used to address issues that have been

reported.

Release Management: In order to make sure the product is ready for deployment and operational usage, quality assurance takes on the role of controlling the software release process.

Post-release Support: QA teams continue to be vigilant after the program is released, keeping an eye out for any problems that end users may raise and making sure that they are fixed quickly. [5]

Test Planning and Strategy

The various risk levels serve as the foundation for defining the test strategy. The test strategy outlines the planning and execution of testing for each risk level. Differentiating between levels enables testing to be conducted at varying degrees of rigor to effectively address the anticipated hazards. This can be accomplished in one of two ways: either by using specialized testing techniques (such as unit testing, use case testing, beta testing, or reviews), or by varying the intensity of these techniques in accordance with various coverage criteria (e.g., use case testing for basic flows and/or alternative flows, or unit testing at 100% branch coverage). A list of applicable quality assurance and testing techniques—that is, techniques for which the organization or the project has enough knowledge, expertise, and tool support—served as the foundation for choosing the right testing methods. The quality management department for the entire organization should make such a list. In order to facilitate conversation regarding which testing and quality assurance techniques are already used in daily work and which ones might be included in the future, we compiled an overview of popular testing and QA approaches. One of the participating firms' testing method selections and how they correspond to different risk levels are exemplified in Fig. 1. In order to further improve the specified testing approaches, this mapping makes it possible to relate them to components. [6]

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Testing techniques	Risk level				Components	A	B	C	D	E	F
	I	II	III	IV	Risk level	I	IV	II	III	I	III
Unit testing (100% branch coverage)				X			X				
Code reviews		X	X	X			X	X	X		X
Manual testing of use cases (base flow)		X						X			
Manual testing of use cases (base + alternative flows)			X	X			X		X		X
Exploratory testing	X			X		X	X			X	
Automated smoke/regression tests			X	X			X		X		X
Beta test phase at selected customers		X	X	X			X	X	X		X

Fig.1 Example catalogue of testing of one of the involved companies. [6]

Risk-based testing, or RBT, is a testing methodology that takes into account the software product's risks as a guiding factor to support decisions made during the entire test process. A risk is something that might have unfavorable effects down the road and is typically described by its impact and likelihood. The chance of a failure linked to a risk occurring determines the likelihood of a failure in software testing, and the cost or severity of a failure in operation determines the impact. A risk item is assigned the risk value or risk exposure that results. When it comes to testing, a risk item is any valuable object (i.e., asset) that is being tested, such as a feature, component, or requirement.

The risk items are normally ranked and categorized into risk levels, creating a risk profile based on the risk exposure values. Decisions made throughout the whole test process, from fundamental activities such as test planning, test design, and test execution to test evaluation, can be supported by the data gathered in the risk profile.

To design and implement a risk-based testing method, the procedure for creating a risk-based test strategy is presented in this section. How testing is set up and carried out at each test level is described in a test strategy. A project- or product-iteration-specific context must be considered when refining the generally relatively generic strategy before implementing it. A concrete test

approach is produced as a result of the refinement, which outlines the many test kinds that must be conducted, the test and quality assurance methodologies to be employed, and the coverage and exit criteria used to track the progress and decide when the test is finished.

An overview of the complete procedure is given in Fig. 2. It is composed of various steps that are either directly related to the development of the risk-based test strategy (bold font) or serve to establish the prerequisites (normal font) for the process by connecting the test strategy development to the related processes (dashed lines) of requirements management, quality management, and defect management. The ensuing subsections provide a detailed description of each phase. [6]

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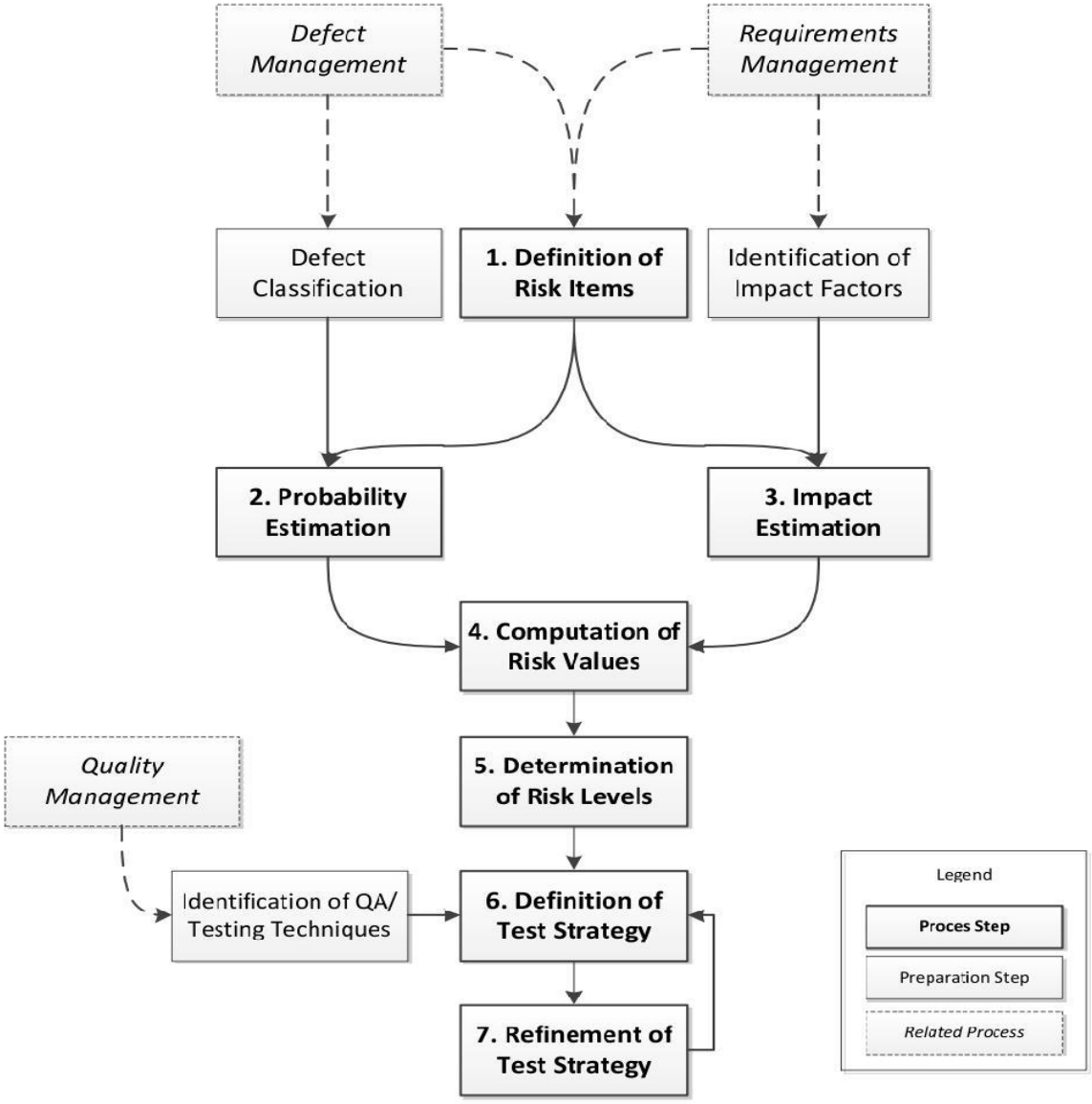

Fig.2 Process for risk-based test strategy development [6]

Adaptability and Flexibility

Initially, climate change adaptation was thought to be rather straightforward. This simplicity resulted from the inquiry procedure that the IPCC institutionalized, which used projections of future climate scenarios from the present climate baseline to evaluate consequences. Next, the

adjustments needed to lessen the impact or to profit from any related advantages were used to measure adaptation. The assessments up until those compiled in the IPCC Fourth Assessment Report were dominated by this climate scenario-driven, or "standard approach."

A number of criticisms that highlight the shortcomings of the conventional method can be summed up as follows:

1. Understanding adaptation as a social process is separate from being able to forecast climate change and its effects.

2. Since social and environmental vulnerability are larger components of susceptibility to climate change, lessening the latter can also reduce vulnerability to climate change.

3. The conventional method separates adaptation to past climate change and other changes in related human-environmental systems from adaptation to current climate change.

4. Understanding climate change is aided by the "deep uncertainty" that exists in relation to future socioeconomic situations and the uncertainty that exists in complex systems.

Various techniques have been devised in the last twenty years to address these uncertainties and constraints Although each has advantages, we would contend that they are best used as techniques within a risk management strategy that is adaptable enough to make use of a variety of techniques. As the Choosing the approaches that work best for a given situation and set of requirements is a challenge. A few are briefly explained here. A method for handling uncertainty is to make better scientific predictions. in particular, of climate-related risks and their effects. For instance, the design and placement of infrastructure, as well as catastrophe mitigation, depend on the projected return intervals for particular risks, such as a one-in-a century flood or storm event.

Assuming a fixed climate, these benchmarks are based on statistical estimations of occurrence frequency and magnitude. A common misconception about climate change planning is that it involves changing such criteria to account for potential future conditions. Large sums of money have been invested in enhancing global climate models' capacity to forecast future climate conditions and, consequently, reduce uncertainty about them. The probability distributions of

future states have been tightened most recently by model performance studies and the application of selected model weighting.These methods can be used to achieve outcomes.

In essence, these initiatives are an effort to increase agreement on "best guess" projections of future climate change and its effects. Nonetheless, there are many who oppose these reductionist methods of managing uncertainty The IPCC reports' emphasis on consensus, has put the spotlight on expected outcomes, which then become anchored via numerical estimates in the minds of policy-makers." Now that the science underlying climate change has gained widespread acceptance, it is equally critical for decision-makers to be aware of the more unlikely scenarios that the consensus may ignore or minimize. Therefore, methods of controlling uncertainty through prediction and optimization may obscure possible outcomes, especially those with serious implications that seem improbable.

Without relying on likelihoods, scenarios can be created to offer a discrete set of tenable assumptions about potential future states. The main defense of them is that they extricate research from being bound to a specific model or normative portrayal of future states or from incorrectly combining such states. Alternatively, any future can be taken into consideration; nonetheless, experts often underestimate the full range of uncertainty associated with complex systems, even with such freedom.

The problem with these scenarios is that researchers have repeatedly refrained from giving climate model scenarios a likelihood, instead treating them more like "if...then" constructions. However, the absence of guidance regarding the possibility of various scenarios has been noted as a potential issue for decision-making. Although scenarios can indicate uncertainty, they may not always explicitly state it.An additional approach involves evaluating the resilience of various adaptations to a wide range of likely climate change scenarios. This is because uncertainties are not entirely resolved and will involve subjectivity, and climate change might very well transpire beyond the range of the projected range supplied by climate modeling. [7]

Most risk assessment techniques use the FMEA method to identify and prioritize the potential causes of failure risks. Although the traditional FMEA method’s calculation is simple, it cannot

handle hesitant information or missing information that a decision-maker provided attribute values. Moreover, the traditional FMEA method does not take into account the subjective and objective weights of the three risk factors. [8]

Challenges and best practices

The challenges that risk based approaches faces are:

1. **Not Using the Correct Risk Metrics**
   A popular risk indicator called value-at-risk, or VaR, only indicates the biggest loss a company has ever experienced. The distribution of losses that are greater than VaR is not indicated by VaR. This would imply that risk management success is not ensured by the use of VaR. The financial market's liquidity affects how well VaR is implemented as well.
2. **Evaluation of Known Hazards**
   Risk managers occasionally make mistakes while appropriately displaying the likelihood and magnitude of losses. Moreover, they might choose the incorrect distribution route. Even so, a financial organization with an infinite number of positions could accurately calculate the distribution related to each position. One of the biggest challenges in risk management is measuring a known risk incorrectly or not at all.
3. **Not taking recognized dangers into account**
   Risk managers can run into difficulties taking into account every risk in a risk management system. Sometimes it's because of the extra cost, and other times it's due to negligence. This occurs as a result of the impossibility of predicting the future.
4. **Incapable of informing upper management about hazards**
   Top management must be informed about the organization's risk status by risk managers. This information must be considered by the board and management when developing a risk management plan. [9-12]

Future trends

New trends and technological advancements that enable businesses to proactively detect, evaluate, and reduce risks will influence risk management in the future. Big data analytics, cybersecurity, artificial intelligence, machine learning, and efficient risk management are important pillars in this shift.

Conclusions

In conclusion, this review underscores the paramount importance of adopting a risk-based approach within Quality Management Systems (QMS) for organizations striving to optimize efficiency and elevate service quality. It accentuates the imperative for establishing standardized definitions of key terms such as "quality risk" and "risk-based thinking in QMS" to foster clarity and facilitate seamless implementation across diverse organizational contexts. Moreover, the review highlights the pivotal role of integrating risk management seamlessly into the Software Development Life Cycle (SDLC) to ensure a holistic approach to quality assurance. By embedding risk assessment methodologies into each phase of the SDLC, organizations can proactively identify and mitigate potential risks, thereby enhancing the overall robustness of their products and services. Furthermore, the review emphasizes the necessity of embracing adaptable strategies to navigate uncertainties and challenges inherent in risk management. By fostering a culture of flexibility and innovation, organizations can effectively respond to evolving risk landscapes and seize opportunities for continuous improvement.

Looking forward, the review anticipates significant advancements in technology, particularly in areas such as big data analytics, cybersecurity, and artificial intelligence, to revolutionize the future of risk management. These innovations hold the promise of enabling organizations to not only detect risks preemptively but also to develop proactive mitigation strategies, thereby fortifying their resilience in an ever-changing business environment. As organizations embark on this journey towards a more robust and proactive approach to risk management, it is essential to recognize the transformative potential of collaboration and knowledge-sharing among stakeholders. By fostering cross-functional communication and leveraging insights from diverse perspectives, organizations can harness collective intelligence to identify emerging risks and capitalize on opportunities for continuous improvement. In essence, the adoption of a risk-based approach in QMS represents a paradigm shift in how organizations conceptualize and manage

quality. By embracing this approach wholeheartedly and remaining vigilant to emerging trends and technologies, organizations can not only enhance their operational efficiency and service quality but also position themselves as industry leaders in an increasingly competitive global marketplace.

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